US 20170290513A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2017/0290513 A1**

O'Reilly et al. (43) **Pub. Date: Oct. 12, 2017**

(54) **INGESTIBLE EVENT MARKER DATA FRAMEWORK**

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(21) Appl. No.: **15/498,396**

(22) Filed: **Apr. 26, 2017**

Related U.S. Application Data

(63) Continuation of application No. 12/522,249, filed on Jul. 6, 2009, filed as application No. PCT/US09/49618 on Jul. 2, 2009.

(60) Provisional application No. 61/079,082, filed on Jul. 8, 2008.

Publication Classification

(51) **Int. Cl.**

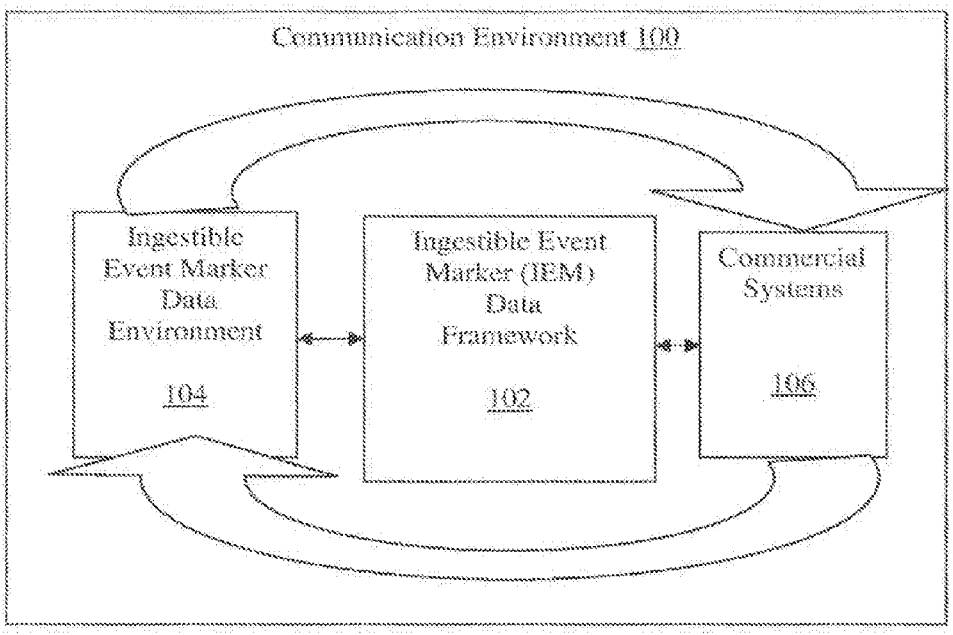
A61B 5/00	(2006.01)
A61B 5/07	(2006.01)
G06F 19/00	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 5/0022*** (2013.01); ***G06F 19/3456*** (2013.01); ***A61B 5/07*** (2013.01); *A61B 5/021* (2013.01)

(57) **ABSTRACT**

The ingestible event marker data framework provides a uniform, comprehensive framework to enable various functions and utilities related to ingestible event marker data (IEM data). The functions and utilities include data and/or information having an aspect of data derived from, collected by, aggregated by, or otherwise associated with, an ingestion event.



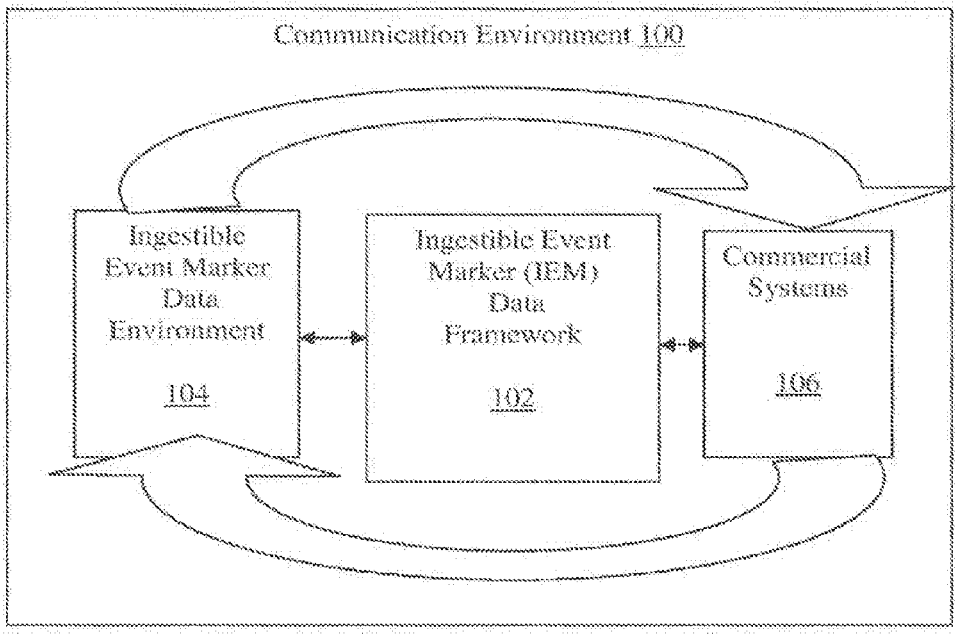

Communication Environment 100
Ingestible Event Marker Data Environment
104
Ingestible Event Marker (IEM) Data Framework
102
Commercial Systems
106

FIG. 1

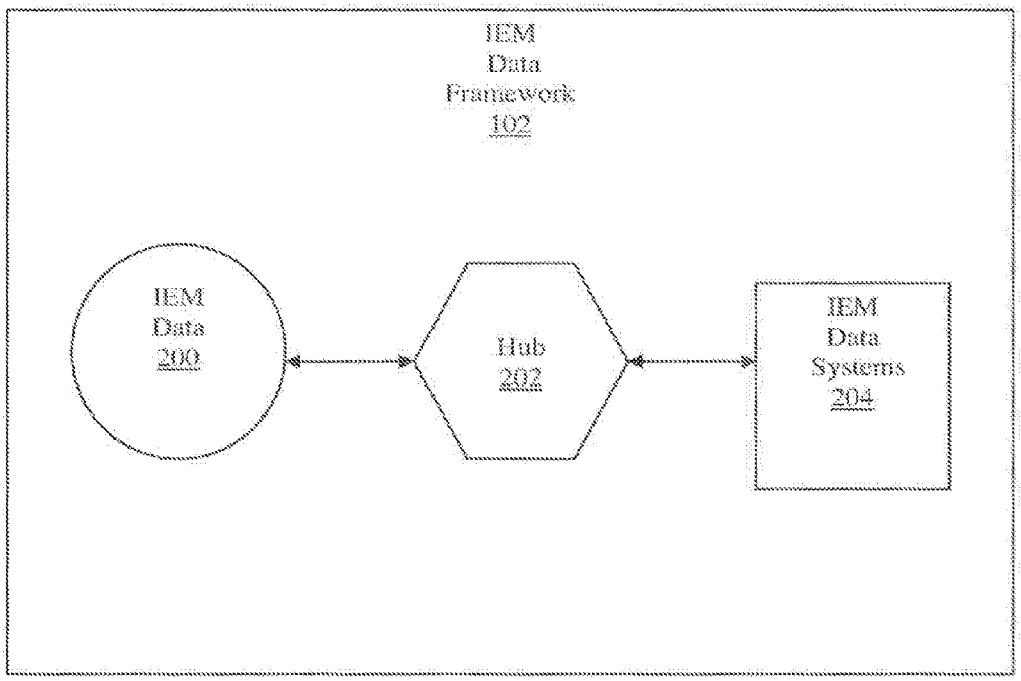

IEM
Data
Framework
102
IEM
Data
200
Hub
202
IEM
Data
Systems
204

FIG. 2

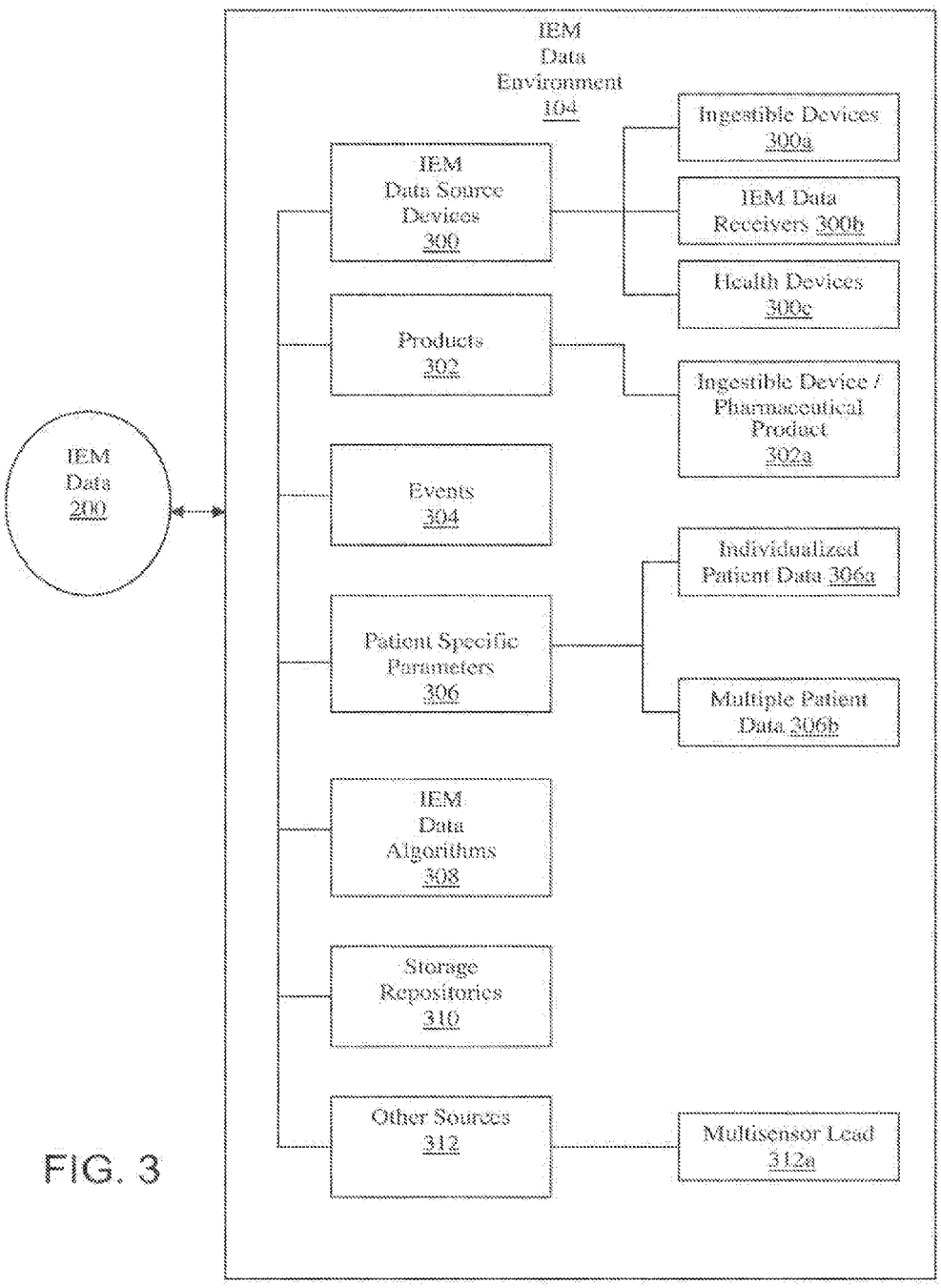

IEM
Data
200
IEM
Data
Environment
104
IEM
Data Source
Devices
300
Products
302
Events
304
Patient Specific
Parameters
306
IEM
Data
Algorithms
308
Storage
Repositories
310
Other Sources
312
Ingestible Devices
300a
IEM Data
Receivers 300b
Health Devices
300c
Ingestible Device /
Pharmaceutical
Product
302a
Individualized
Patient Data 306a
Multiple Patient
Data 306b
Multisensor Lead
312a

FIG. 3

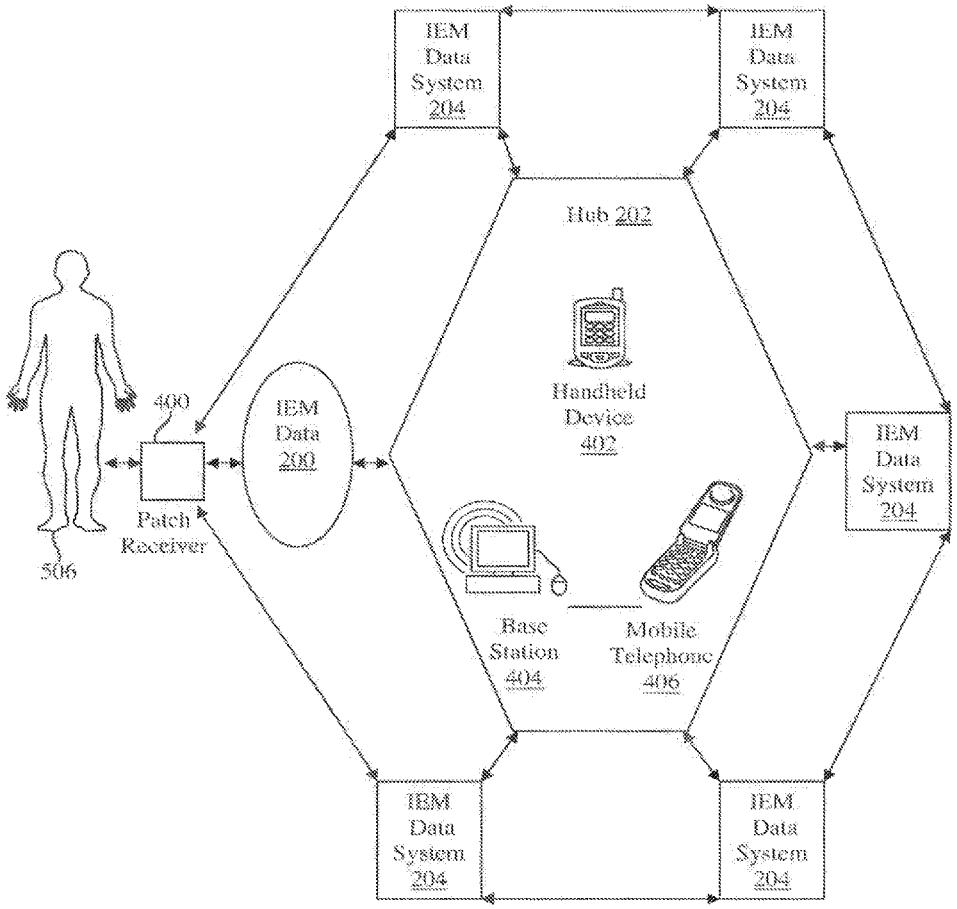

IEM Data System 204
IEM Data System 204
Hub 202
Handheld Device 402
IEM Data 200
400
Patch Receiver
506
IEM Data System 204
Base Station 404
Mobile Telephone 406
IEM Data System 204
IEM Data System 204

FIG. 4

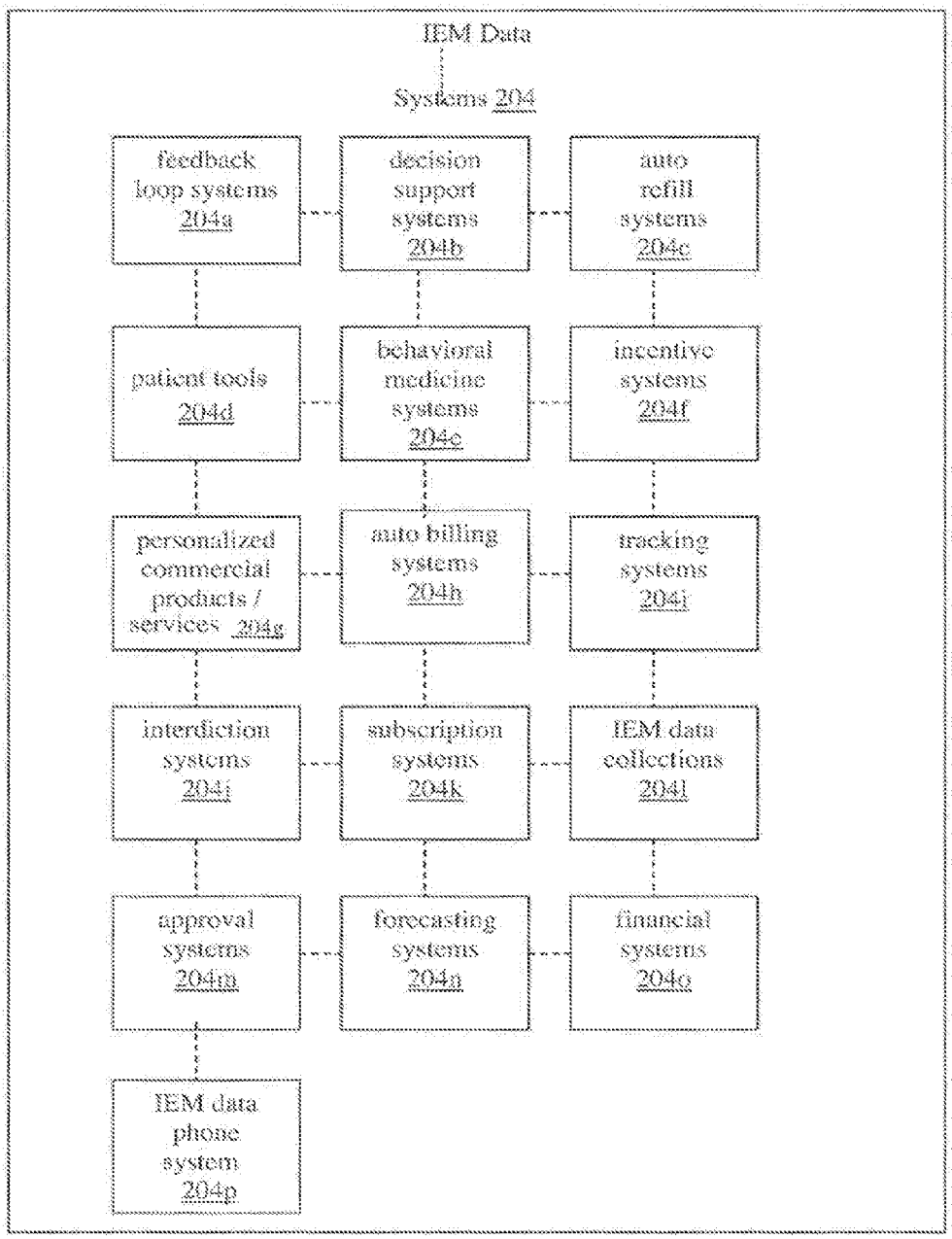

IEM Data
Systems 204
feedback loop systems 204a
decision support systems 204b
auto refill systems 204c
patient tools 204d
behavioral medicine systems 204e
incentive systems 204f
personalized commercial products / services 204g
auto billing systems 204h
tracking systems 204i
interdiction systems 204j
subscription systems 204k
IEM data collections 204l
approval systems 204m
forecasting systems 204n
financial systems 204o
IEM data phone system 204p

FIG. 5

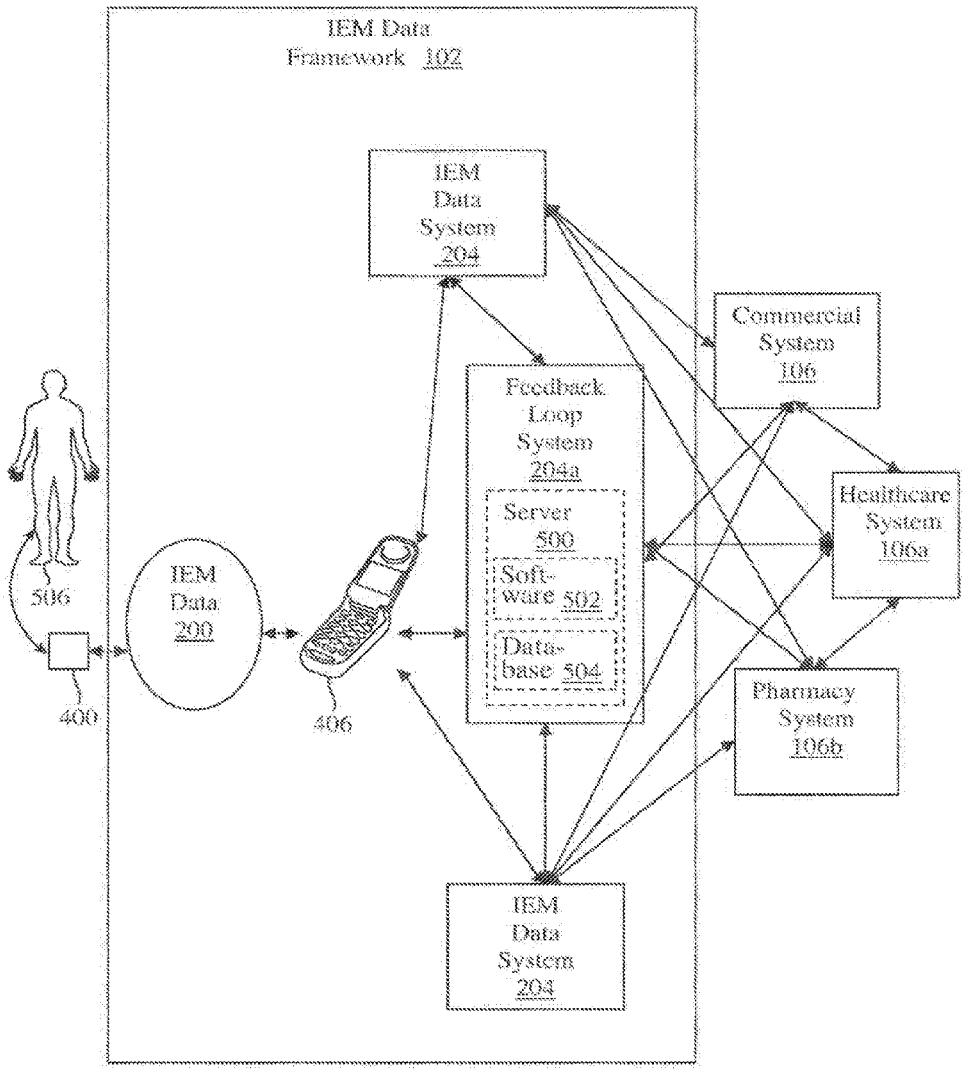

IEM Data Framework 102
IEM Data System 204
Commercial System 106
Feedback Loop System 204a
Server 500
Soft-ware 502
Data-base 504
Healthcare System 106a
Pharmacy System 106b
IEM Data 200
506
400
406
IEM Data System 204

FIG. 6

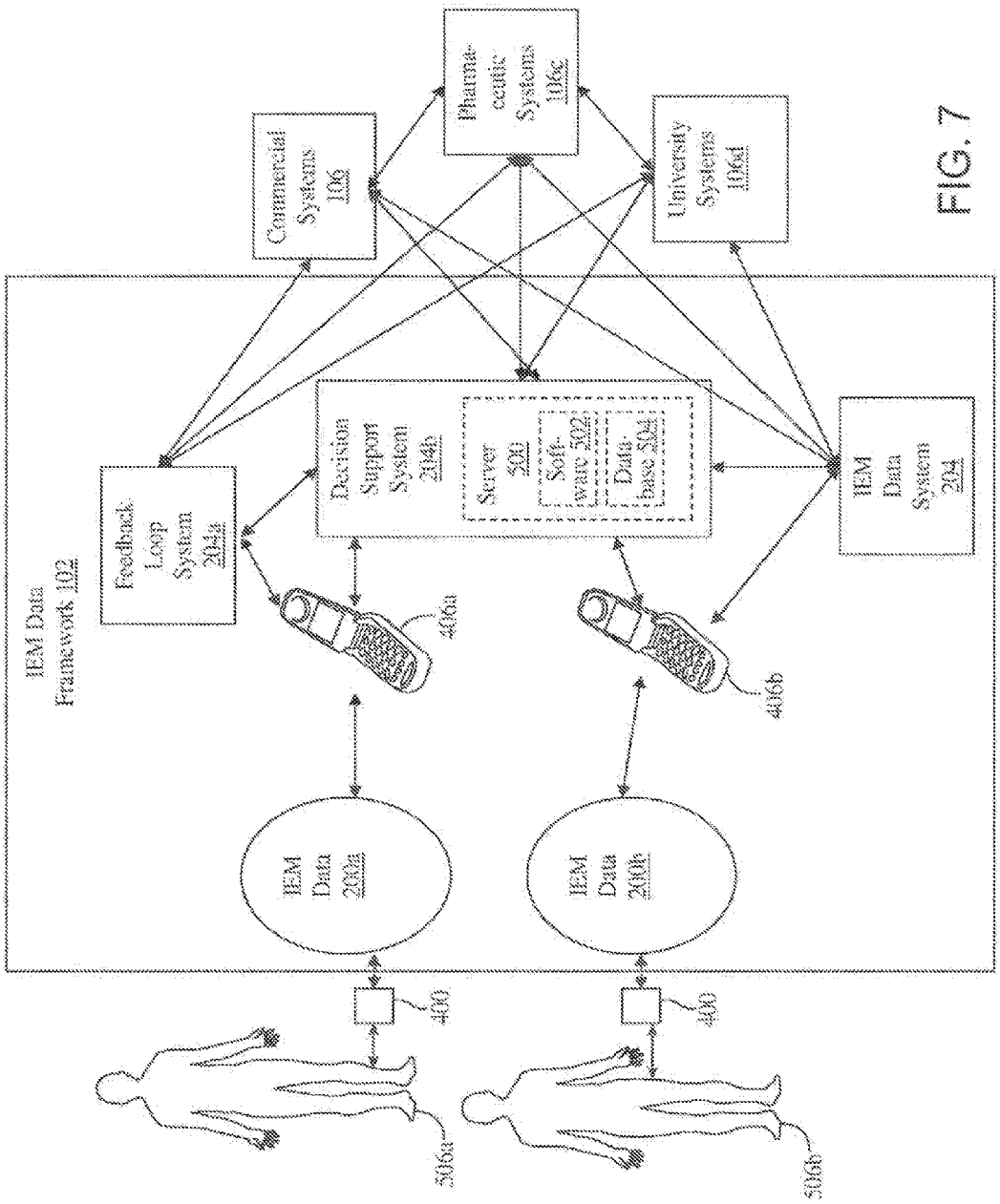

Pharma-ceutic Systems 106c
Commercial Systems 106
University Systems 106d
IEM Data Framework 102
Feedback Loop System 204a
Decision Support System 204b
Server 502
Soft-ware 302
Data base 504
IEM Data System 204
406a
406b
IEM Data 200a
IEM Data 200b
400
400
308a
308b

FIG. 7

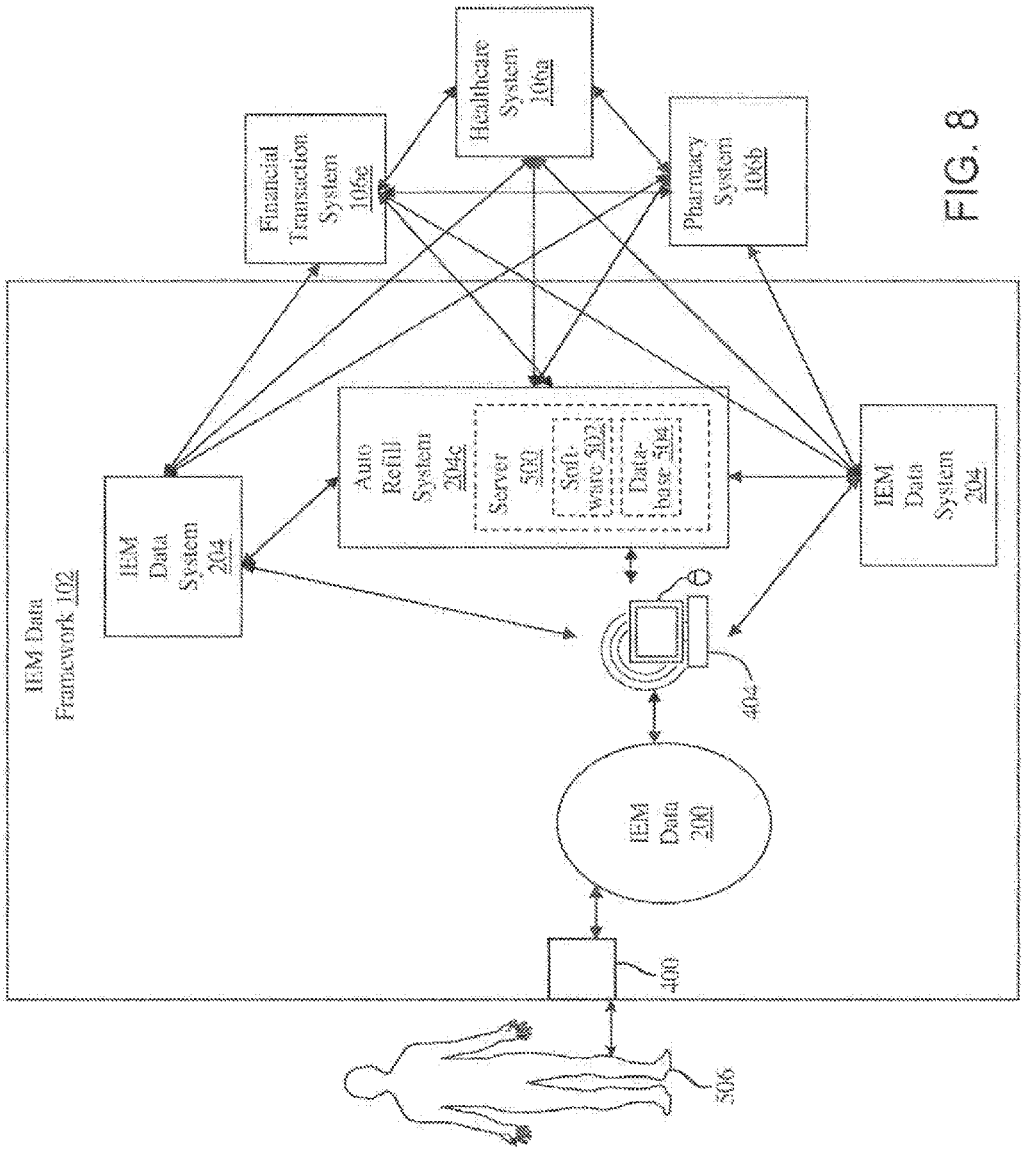

Healthcare System 106a
Financial Transaction System 106c
Pharmacy System 106b
IEM Data Framework 102
IEM Data System 204
Auto Refill System 204c
Server 300
Soft-ware 302
Data-base 304
IEM Data System 204
404
IEM Data 200
400
306

FIG. 8

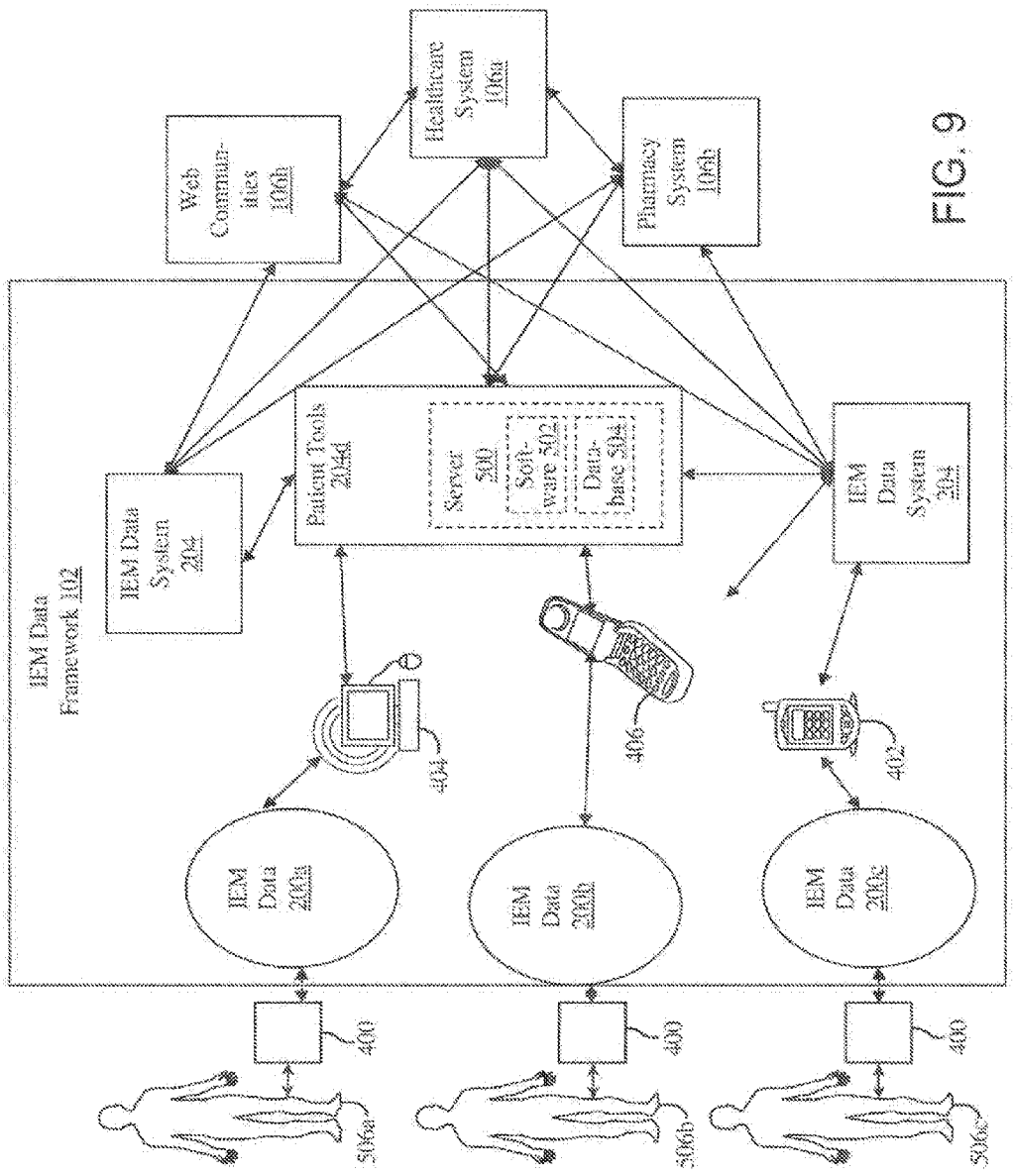

Healthcare System 106a
Web Communities 106b
Pharmacy System 106c
IEM Data Framework 102
IEM Data System 204
Patient Tools 204d
Server 500
Software 502
Database 504
IEM Data System 204
404
406
402
IEM Data 208a
IEM Data 208b
IEM Data 208c
400
400
400
506a
506b
506c

FIG. 9

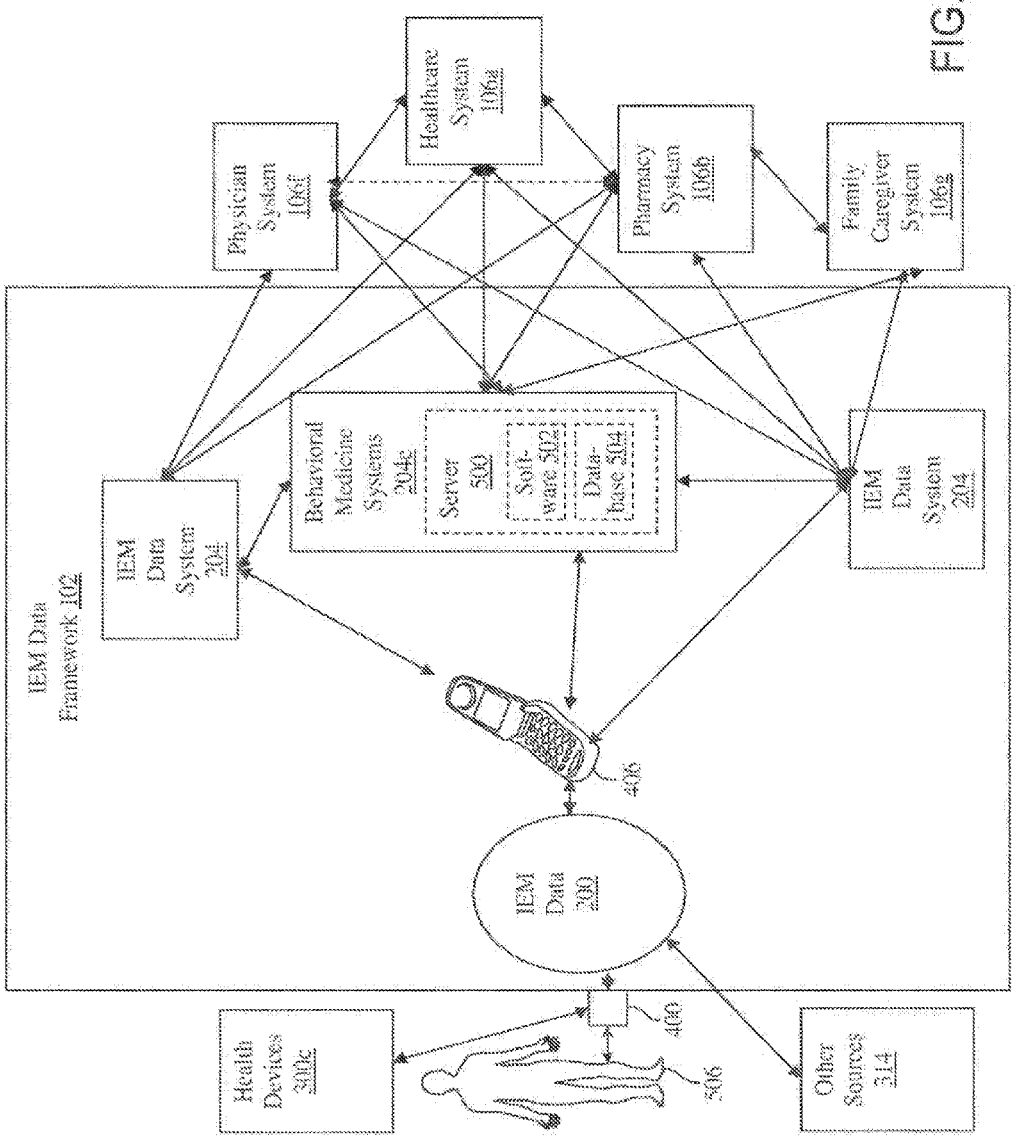

IEM Data Framework 102
IEM Data System 204
Behavioral Medicine Systems 204c
Server 500
Software 502
Database 504
IEM Data System 204
Physician System 106f
Healthcare System 106a
Pharmacy System 106b
Family Caregiver System 106e
406
IEM Data 200
400
506
Health Devices 302c
Other Sources 314

FIG. 10

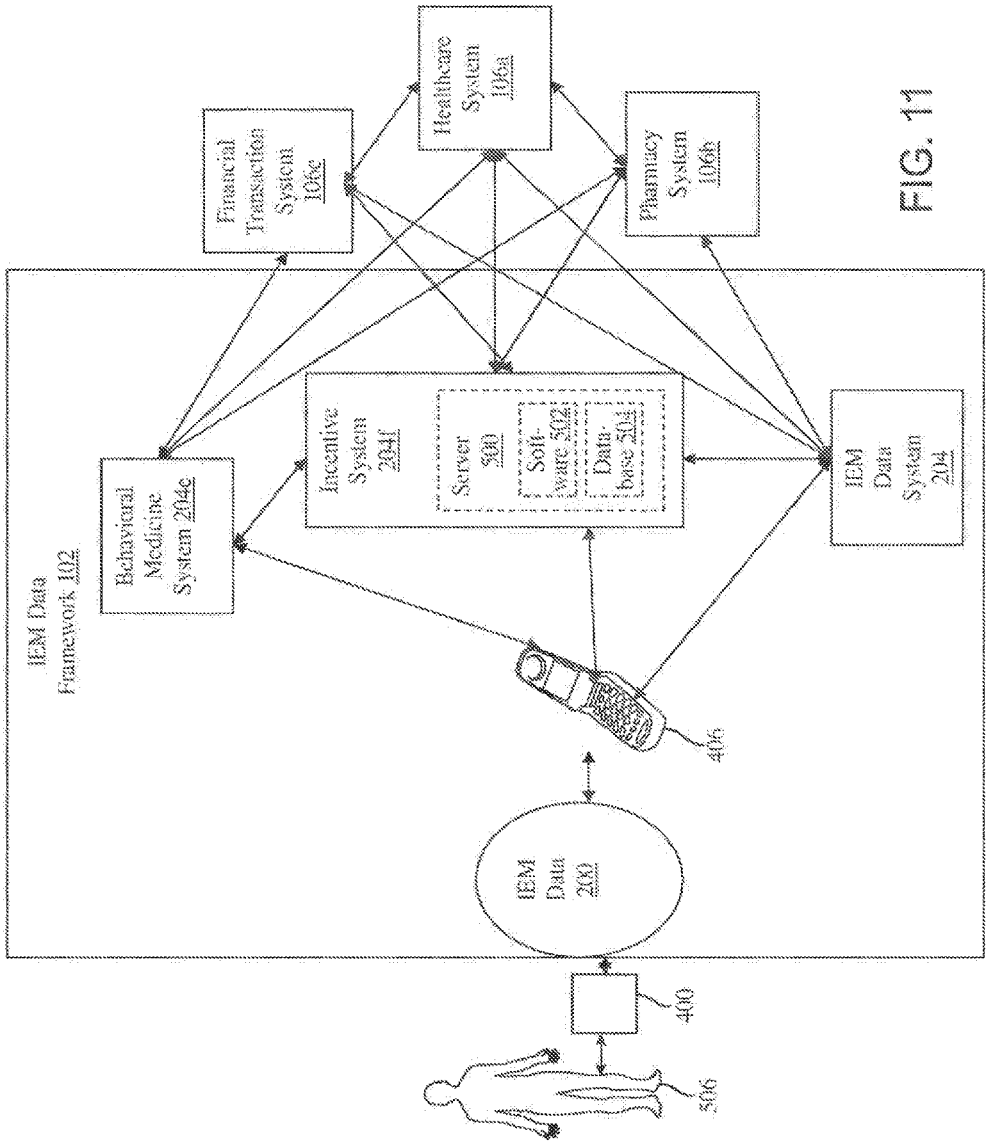

IEM Data Framework 102
Behavioral Medicine System 204e
Incentive System 204f
Server 500
Software 502
Database 504
IEM Data System 204
Financial Transaction System 106c
Healthcare System 106a
Pharmacy System 106b
406
IEM Data 200
400
506

FIG. 11

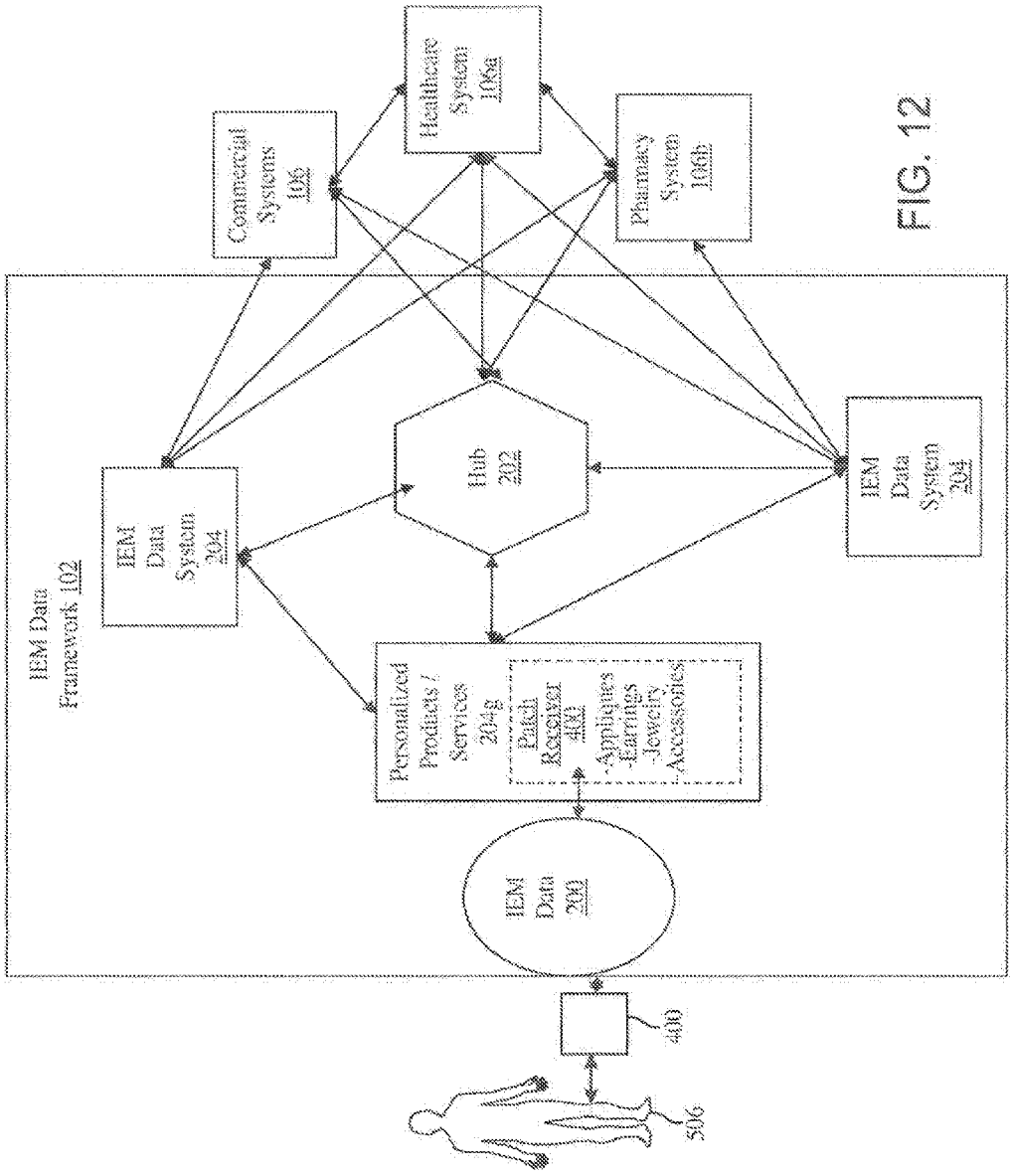

Healthcare System 108a
Commercial Systems 106
Pharmacy System 108b
IEM Data Framework 102
IEM Data System 204
Hub 202
IEM Data System 204
Personalized Products / Services 204g
Patch Receiver 400
Antiques Earrings Jewelry Accessories
IEM Data 200
400
506

FIG. 12

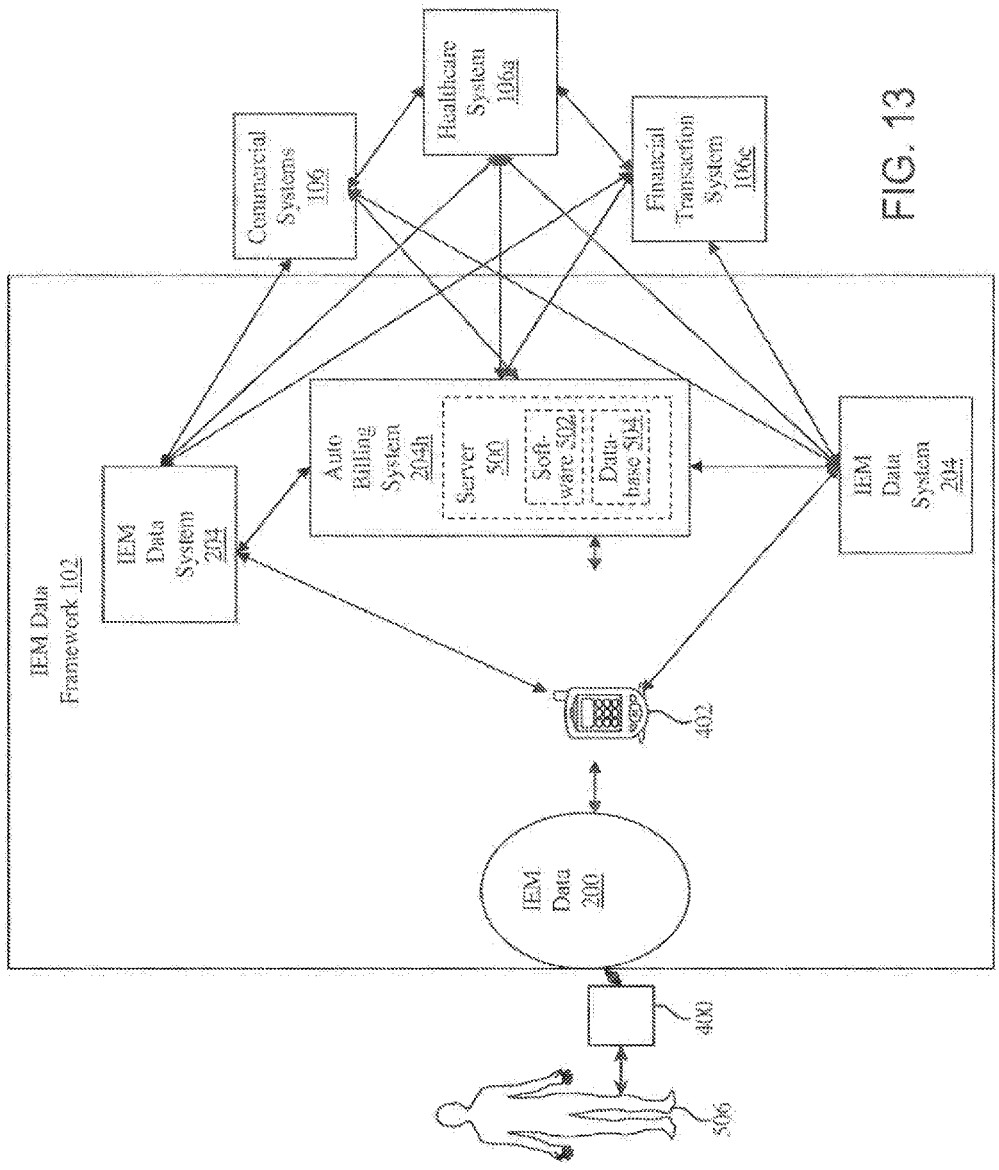

Healthcare System 106a
Commercial System 106
Financial Transaction System 106c
IEM Data Framework 102
IEM Data System 204
Auto Billing System 204b
Server 500
Soft-ware 502
Data-base 504
IEM Data System 204
402
IEM Data 200
400
506

FIG. 13

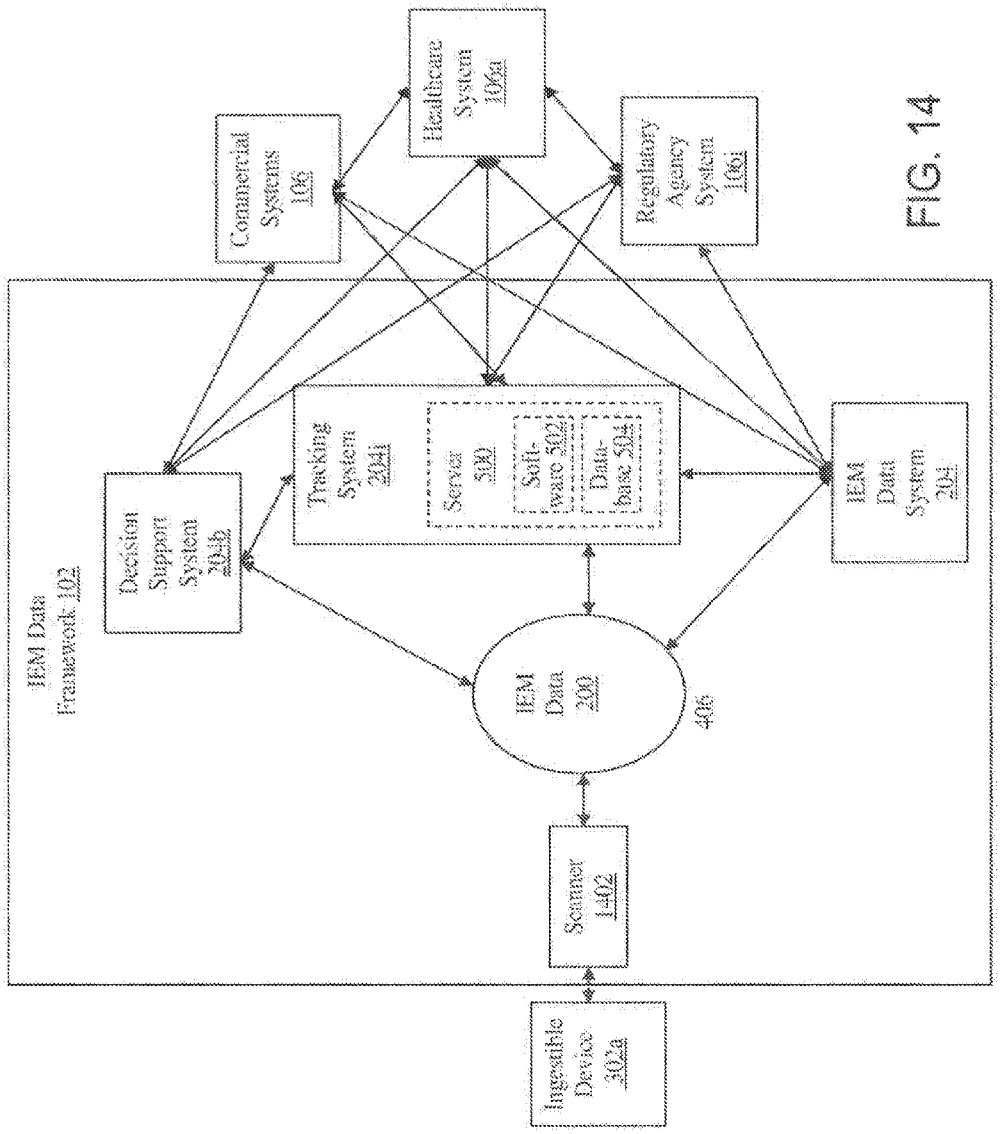

Healthcare System 106a
Commercial Systems 106
Regulatory Agency System 106i
IEM Data Framework 102
Tracking System 204
Server 300
Software 302
Database 304
Decision Support System 204b
IEM Data System 204
IEM Data 200
406
Scanner 1402
Ingestible Device 202a

FIG. 14

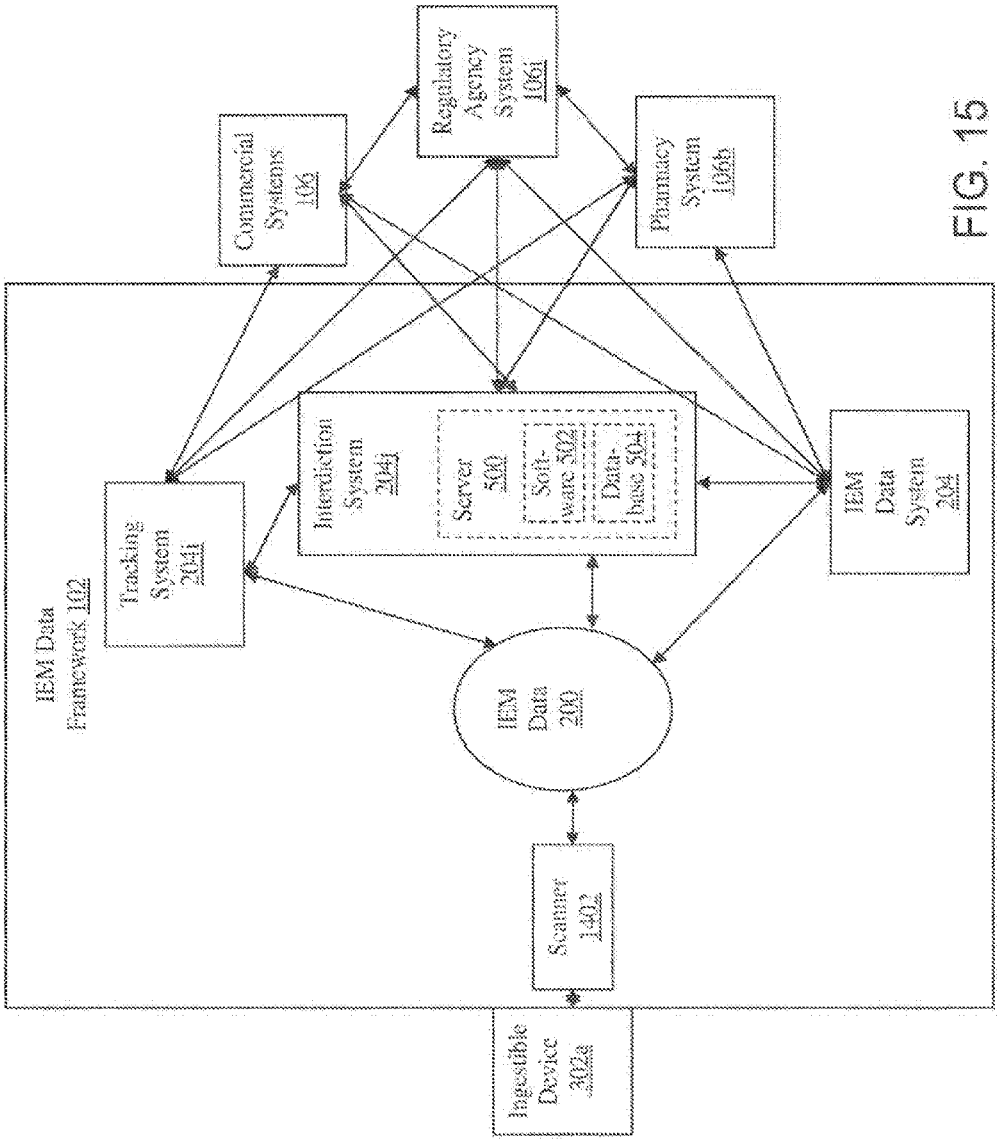

Regulatory Agency System 106i
Commercial Systems 106
Pharmacy System 106b
IEM Data Framework 102
Tracking System 204i
Interaction System 204j
Server 500
Software 502
Database 504
IEM Data System 204
IEM Data 200
Scanner 102a
Ingestible Device 302a

FIG. 15

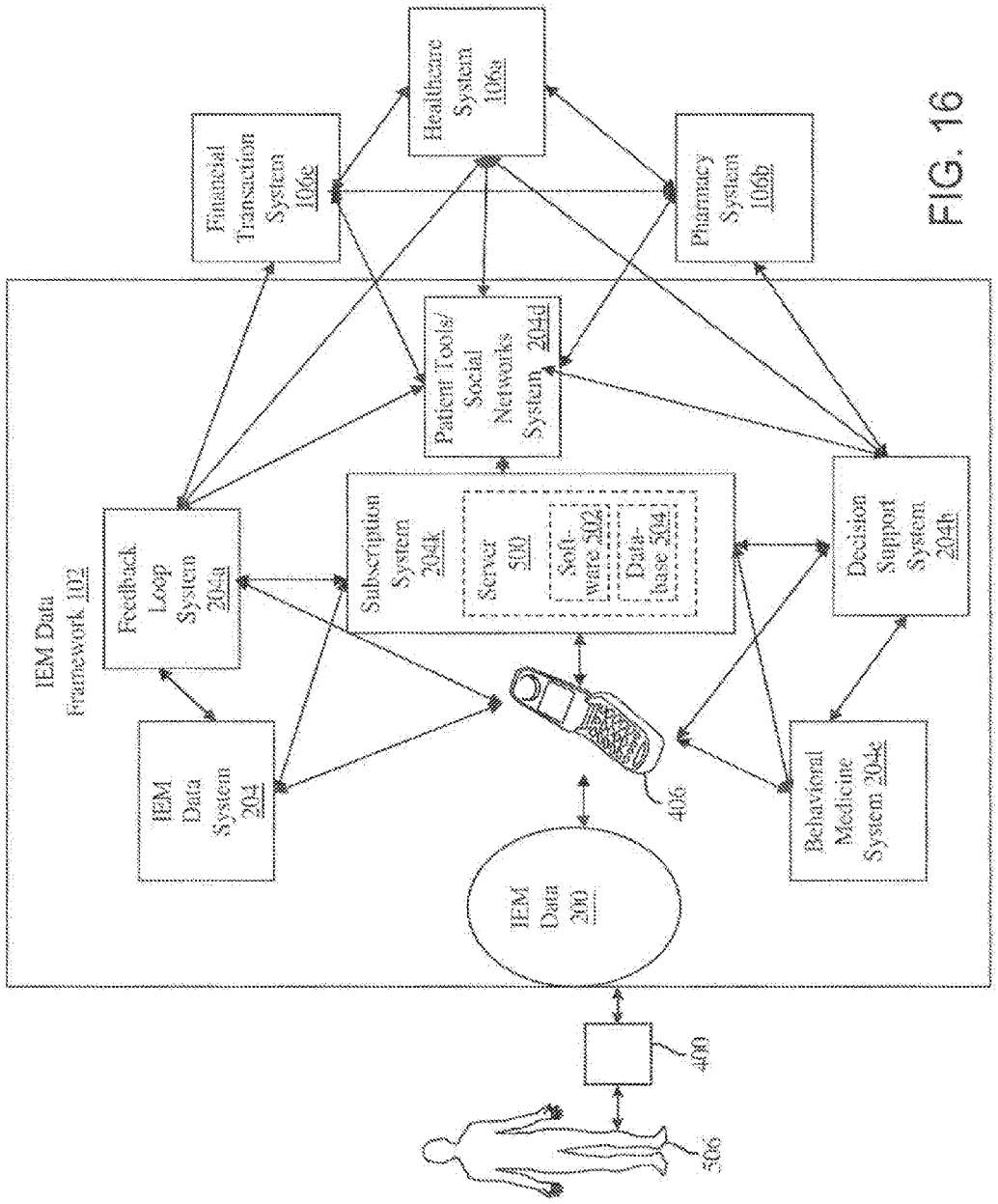

Healthcare System 106a
Financial Transaction System 106c
Pharmacy System 106b
Patient Tools/ Social Networks System 204d
IEM Data Framework 102
Feedback Loop System 204a
Subscription System 204k
Server 510
Soft-ware 502
Data-base 504
Decision Support System 204h
IEM Data System 204
406
Behavioral Medicine System 204e
IEM Data 200
400
506

FIG. 16

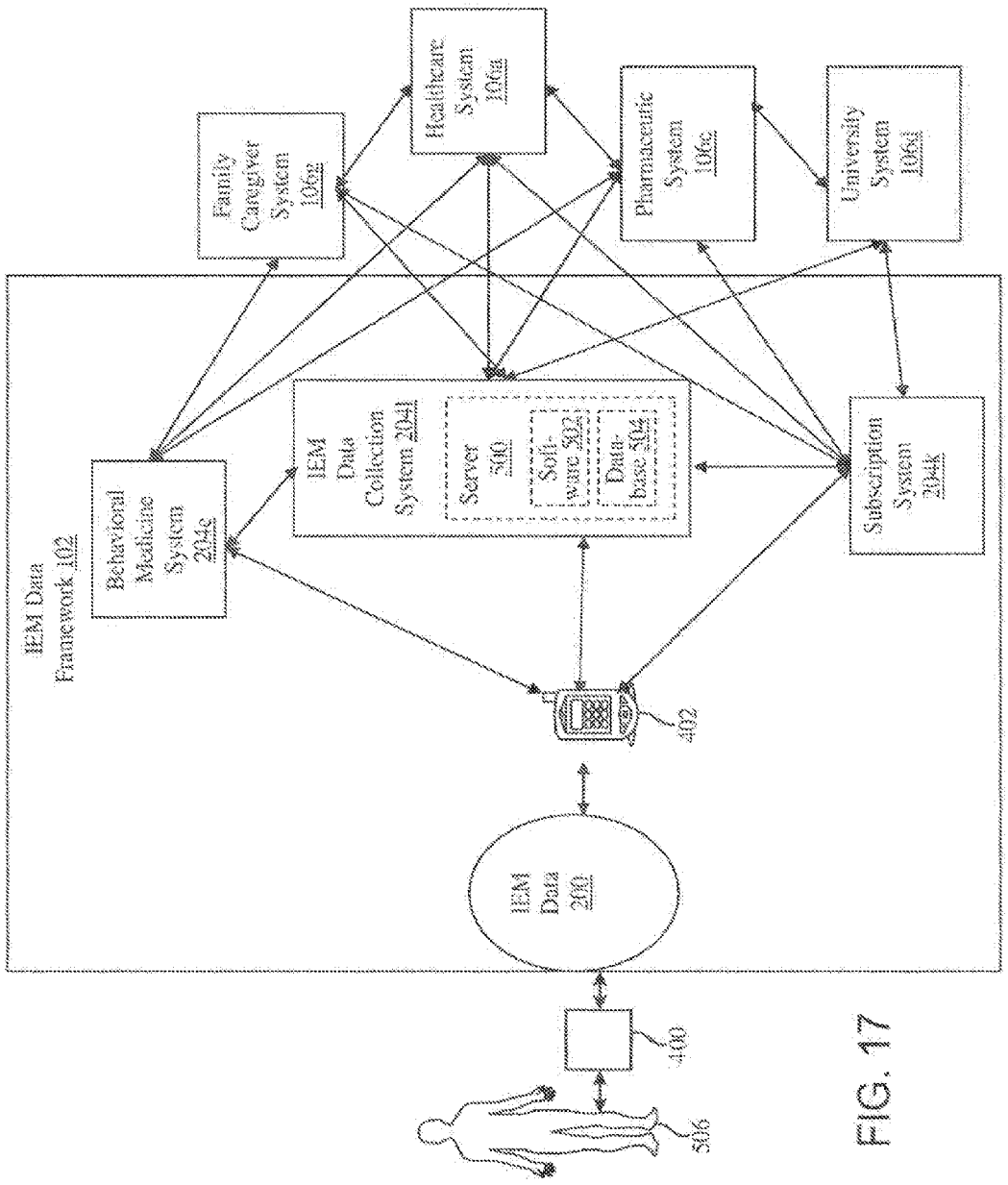

Healthcare System 106a
Family Caregiver System 106e
Pharmaceutic System 106c
University System 106d
IEM Data Framework 102
IEM Data Collection System 204f
Server 500
Software 302
Database 304
Behavioral Medicine System 204e
Subscription System 204k
402
IEM Data 200
400
506

FIG. 17

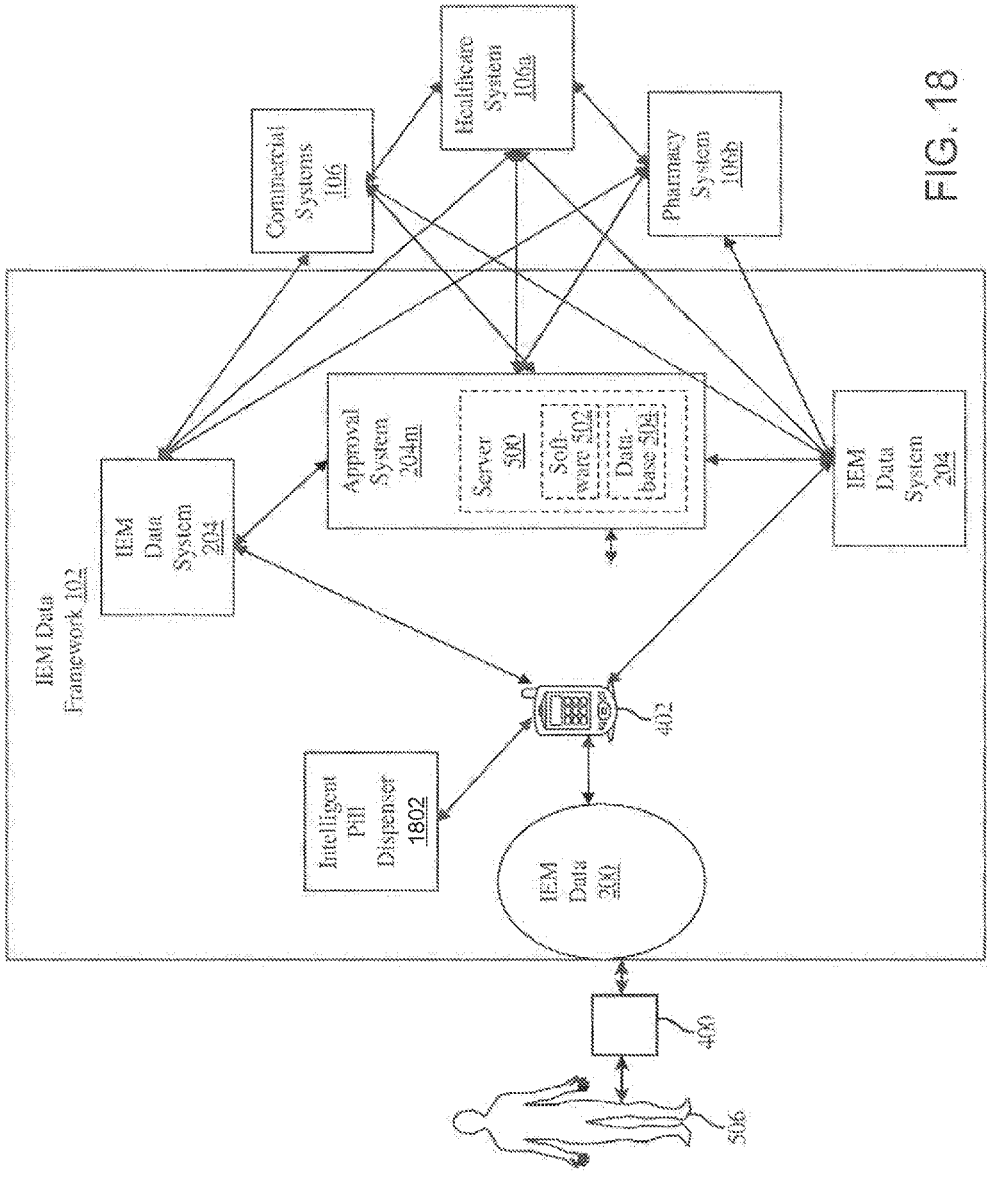

Healthcare System 108a
Commercial Systems 106
Pharmacy System 108b
Approval System 204m
Server 500
Soft-ware 502
Data-base 504
IEM Data System 204
IEM Data System 204
IEM Data Framework 102
Intelligent Pill Dispenser 1802
IEM Data 206
402
400
506

FIG. 18

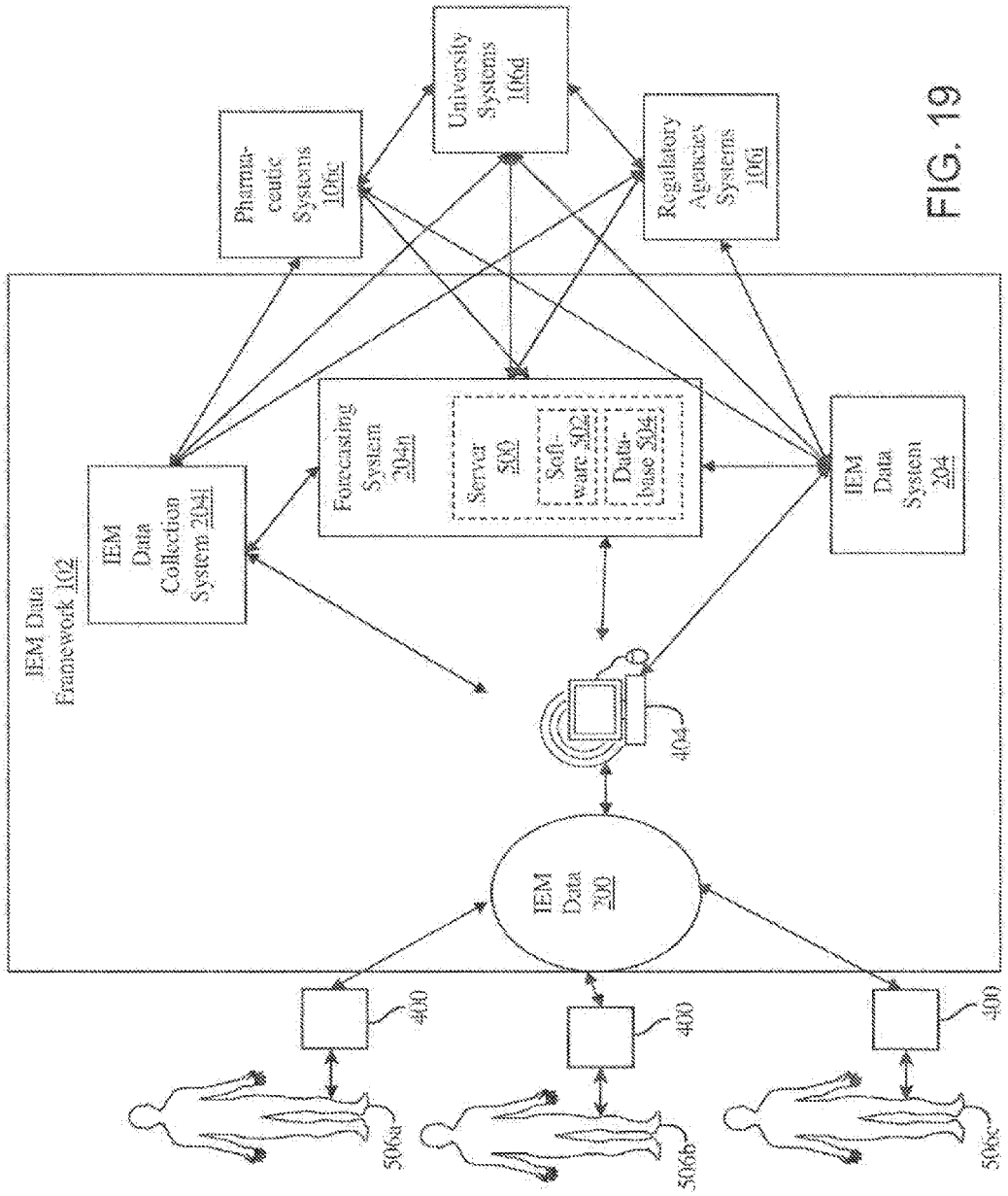
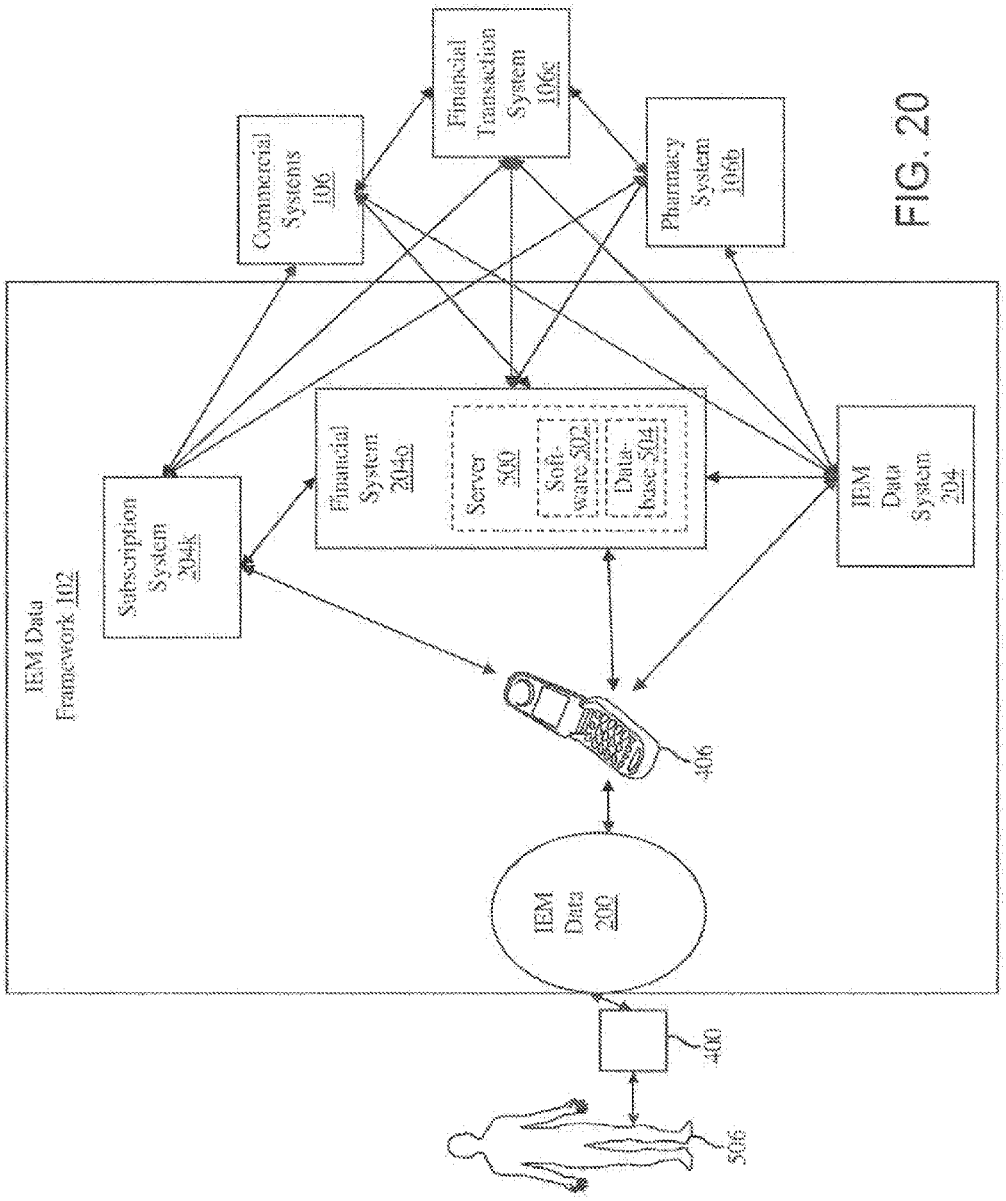

University Systems 106d
Pharma-ceutic Systems 106c
Regulatory Agencies Systems 106i
IEM Data Framework 102
IEM Data Collection System 204i
Forecasting System 204n
Server 300
Soft-ware 302
Data-base 304
IEM Data System 204
404
IEM Data 200
400
400
400
506a
506b
506c

FIG. 19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Commercial Systems 106
Pharmacy System 106b
Subscription System 204k
Financial System 204o
Server 300
Software 302
Database 304
IEM Data System 204
406
IEM Data 200
400
506

FIG. 20

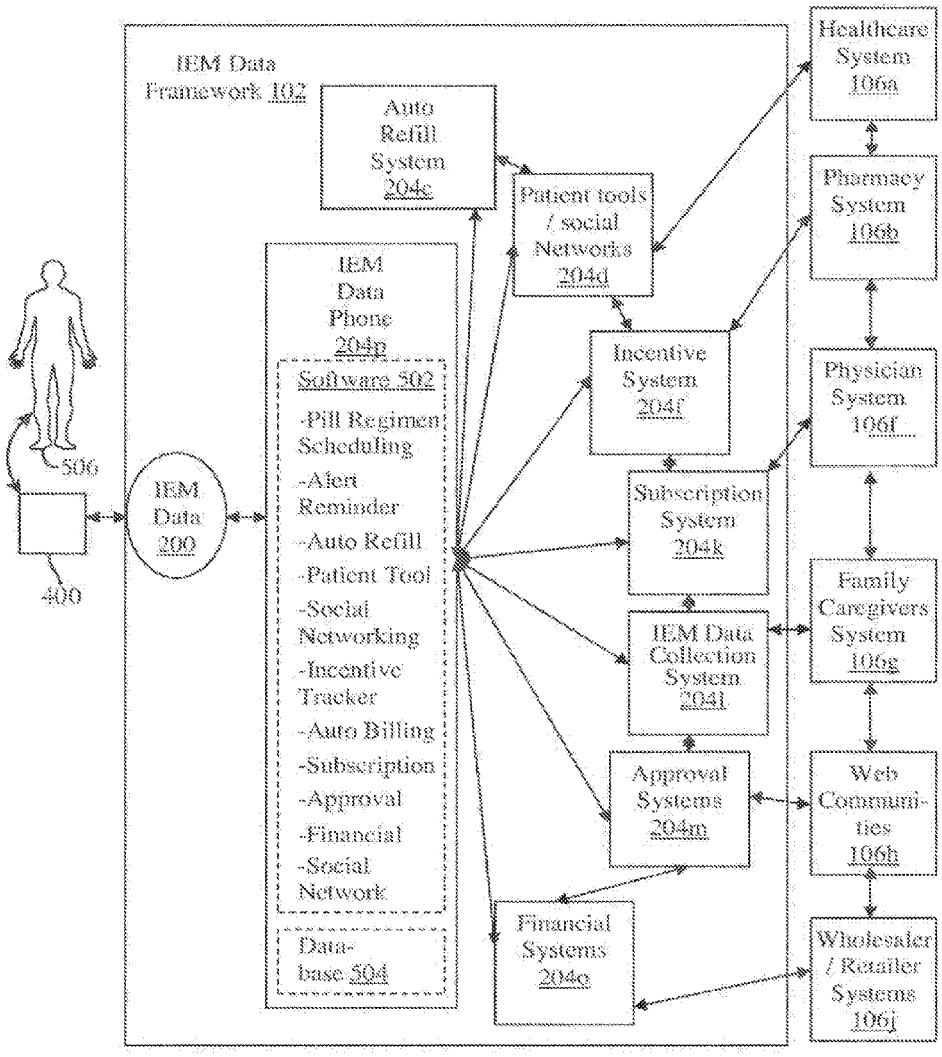
IEM Data Framework 102
Auto Refill System 204c
Patient tools / social Networks 204d
IEM Data Phone 204p
Software 502
-Pill Regimen Scheduling
-Alert Reminder
-Auto Refill
-Patient Tool
-Social Networking
-Incentive Tracker
-Auto Billing
-Subscription
-Approval
-Financial
-Social Network
Data-base 504
Incentive System 204f
Subscription System 204k
IEM Data Collection System 204l
Approval Systems 204m
Financial Systems 204o
IEM Data 200
506
400
Healthcare System 106a
Pharmacy System 106b
Physician System 106f
Family Caregivers System 106g
Web Communi-ties 106h
Wholesaler / Retailer Systems 106j

FIG. 21

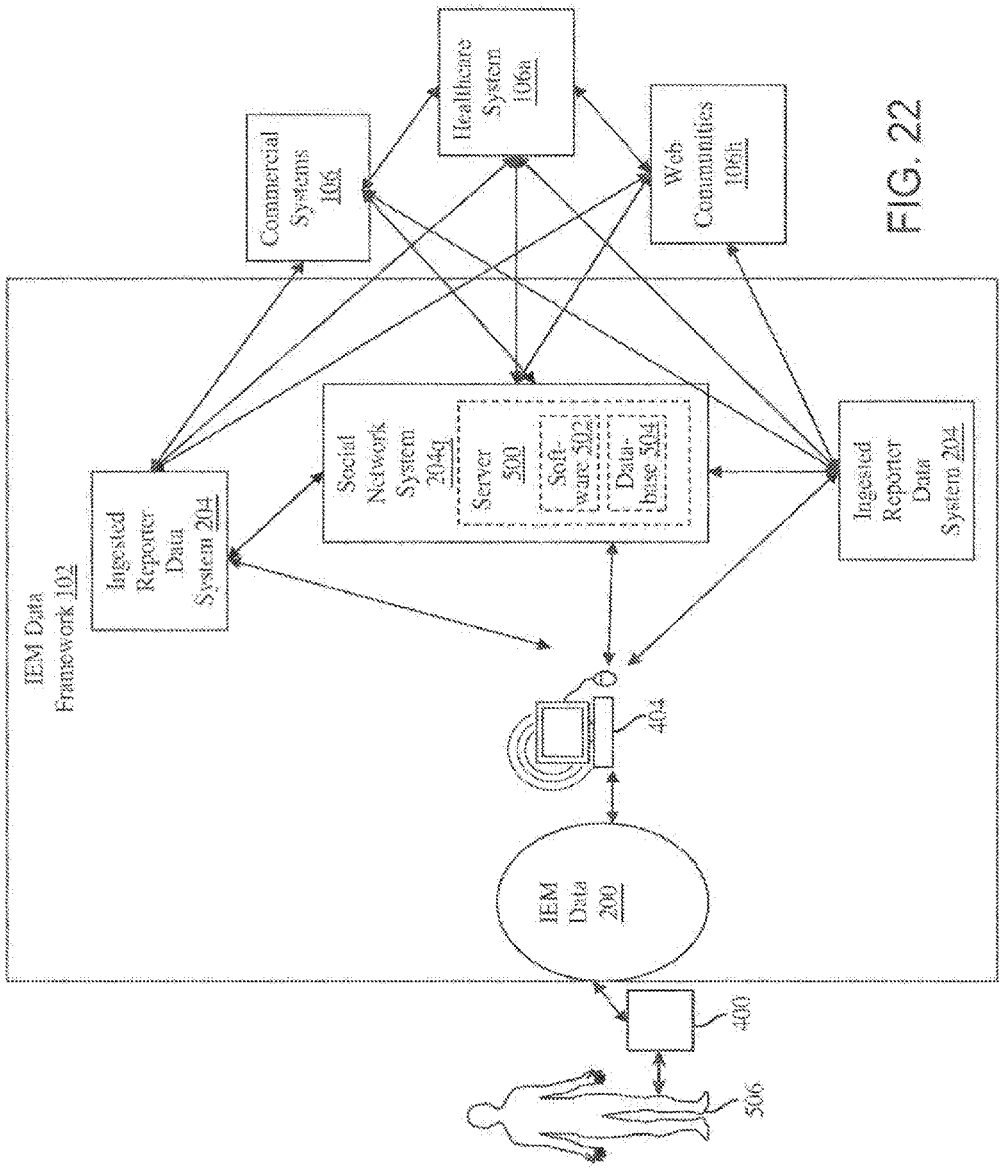
Healthcare System 106a
Commercial Systems 106
Web Communities 106b
IEM Data Framework 102
Ingested Reporter Data System 204
Social Network System 204a
Server 500
Software 502
Database 504
Ingested Reporter Data System 204
404
IEM Data 200
400
506

FIG. 22

INGESTIBLE EVENT MARKER DATA FRAMEWORK

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] Pursuant to 35 U.S.C. §119 (e), this application claims priority to the filing date of U.S. Provisional Patent Application Ser. No. 61/079,082 filed on Jul. 8, 2008; the disclosure of which application is herein incorporated by reference.

FIELD OF THE INVENTION

[0002] The present invention relates generally to the technical fields of ingestible devices and communications. More specifically, and in various example embodiments, the present invention relates to a method, article, and system of generating, collecting, managing, distributing, and otherwise utilizing information associated with ingestible events and responses to the ingestible events.

BACKGROUND

[0003] Information related to personal events is widely needed in various pursuits. A personal event is an event that is specific to an individual. Examples of personal events include onset of a physiologic parameter of interest, ingestion of a therapeutic agent, etc.

[0004] There are many instances where one may want to note a personal event. Examples of such instances include onset of one or more physiologic parameters of interest including appearance of disease symptoms, administration of medication, ingestion of certain types of foods, commencement of an exercise regimen, ingestion of certain substance, etc.

[0005] A variety of different methods and technologies have been developed to note a personal event. For example, techniques have been developed in which individuals can manually record data in a log or physically enter data via a computer device.

[0006] The accuracy of such notations may be dependent on the accuracy of data input, the accuracy of proxies used as actual data substitutions, etc. As a result, inaccuracies may occur.

[0007] In one example, an individual may suffer from one or multiple health conditions that require therapy with multiple medications. The multiple medications may be prescribed according to an intricate dosing schedule. The complexities associated with multiple health conditions, multiple medication therapies, and intricate dosing schedules may confuse the patient, resulting in inaccurate data capture.

[0008] In one example, the individual may have physical or cognitive deficits which may result in difficulties inputting and capturing data. The individual may forget to enter the data, or may enter the data incorrectly.

[0009] In one example, the individual may not wish to be inconvenienced and thus may intentionally refuse to enter the data. Conversely, the individual may unintentionally or intentionally enter/record data which is completely inaccurate. For example, the individual may receive periodic, prescheduled reminders to take some medication. The reminders are unable to take into account actual ingestion of the medication. If the individual has already taken the medication, the reminder is both moot and likely to inconvenience the individual. If the medication has not been taken, an inconvenient or unneeded reminder or alert may prompt the user to enter data or send a message advising that the medication has been taken just to quell the alarm while not actually taking the medication. The individual may intentionally leave out portions of the data.

[0010] In one example, proxies for data and information may also be inaccurate. For example, "intelligent" medication containers may contain microchips that sense opening of the medication container. From the sensed act of opening the container, an inference may be drawn that medication associated with the medication container has been ingested. The inference may be inaccurate, however, as medication is not necessarily ingested by virtue of opening a medication container.

[0011] The above-instances may ripen into further issues if particular parties besides the individual wish to use the individual's personal event data. Examples of users and potential users (sometimes collectively referred to herein as "party" or "parties") of personal event data include family and professional caregivers; communication companies; government agencies, e.g., agencies associated with government provided healthcare coverage; private insurance providers; Food and Drug Administration (FDA); Drug Enforcement Administration (DEA); US Bureau of Alcohol, Tobacco, and Firearms (ATF); care providers; medical device manufacturers; patients; clinicians; pharmaceutical manufacturers; pharmacies; web communities; software providers; marketing and financial analysts; and insurance companies.

[0012] Competing interests may exist between an individual's privacy interests in personal event data and the acquisition and appropriation of the personal event data by third parties.

[0013] Further, various parties may have a compelling interest in receipt of accurate and comprehensive data, e.g., useful data, either in isolated form (data germane to a particular individual) or empirical form (aggregated data from various sources, various individuals, various personal events of an individual, etc.)

[0014] In many circumstances, however, accurate personal event data are not available. The party may have access to faulty data or a crude approximation of the information sought, as discussed above. Thus, the party must rely on such crude proxies to formulate a conclusion. It follows, then, that such conclusions may themselves be skewed or inaccurate. Actions taken in reliance on such conclusions may prove misguided, error-prone, and/or harmful.

[0015] To illustrate, a healthcare provider or family member may receive a message from a patient indicating that the patient has taken the medication when, in fact, the patient is merely providing the message without having actually ingested the medication. If the healthcare provider notices changes in the patient's symptoms in close temporal proximity to receipt of the flawed information suggesting medication ingestion, the healthcare provider may mistakenly conclude that the patient's symptoms are a result of the medication ingestion. Based on the mistaken conclusion, the healthcare provider may adjust the medication dosage in an attempt to alleviate the symptoms, perhaps to the patient's detriment.

[0016] Of note, the more widely propagated and aggregated the inaccurate data, the more prolific the spread of and reliance on error-associated data and conclusions drawn therefrom.

[0017] In addition, recipients of the personal event data may wish to timely receive and utilize such information via a user-friendly, reliable and sophisticated means. The recipients may wish to receive and/or utilize information in discrete areas, integrate the personal event information with other data, and use the personal event information for various purposes.

[0018] Examples of various purposes include refining and optimizing data such as patient population data; incentivizing individuals or groups based on personal event data, e.g., ingestible event marker data ("IEM data"); corroborating and advancing decisions; supporting stakeholders' decisions; using IEM data in personalized products and services, e.g., user applications on a mobile telephone; auto refilling prescription medications; managing pharmaceutical life cycle systems and controlled substances; compiling and delivering IP news and information feeds; accessing open sources of anonymized patient population data; determining eligibility and approval for refills, insurance coverage, etc.; using patient tools; participating in social network systems; analyzing aggregated data to derive and/or generate predictive information; supporting and enabling financial transactions; identifying direct and indirect causal failure points in treatment and predict corrective action; and providing dynamic, accurate calendaring/scheduling functions.

[0019] Finally, parties may also wish to access personal event data in conjunction with existing systems, e.g., commercial systems such as automated pharmacy systems, banking and financial systems, etc.

[0020] As can be seen, methods and systems are needed to seamlessly collect, manage, and distribute personal event data to various parties and systems.

[0021] Therefore, there is a need for controlled collection, management, and delivery of accurate personal event data to multi-profile parties for various purposes.

BRIEF SUMMARY OF THE INVENTION

[0022] The ingestible event marker data framework provides a uniform, comprehensive framework to enable various functions and utilities related to ingestible event marker data (IEM data). The functions and utilities include data and/or information having an aspect of data derived from, collected by, aggregated by, or otherwise associated with, an ingestion event. In one example, the IEM data are generated via an ingested device. The term "ingested device" includes any device, mechanism, structure, combined structure, or object capable of ingestion by a human subject or a non-human subject.

[0023] The IEM data framework is highly scalable and integratable with various existing systems, e.g., systems having computer-related component(s). Specific examples of such systems include pharmacy systems, communication systems, financial and banking systems, school systems, medical systems, government agencies, web communities, and personal computer systems. Such existing systems are herein collectively referred to as "commercial systems".

[0024] The IEM data framework enables multiple and various types of implementations. The implementations include various configurations of hardware, software, communication components, and/or data. For example, in one aspect, the IEM data framework is implemented with a basic complement of core components; namely, ingestible event marker data; a hub to receive the ingestible event marker data; and at least one ingestible event marker data system to receive, directly or indirectly, the ingestible event marker data from the hub.

BRIEF DESCRIPTION OF THE FIGURES

[0025] FIG. **1** provides a diagrammatic representation of a communication environment including an IEM data framework, according to one embodiment.

[0026] FIG. **2** provides a diagrammatic representation of the IEM data framework of FIG. **1**, according to one embodiment.

[0027] FIG. **3** illustrates IEM data and an IEM data environment associated with the IEM data framework of FIG. **2**, according to one embodiment.

[0028] FIG. **4** illustrates a hub associated with the IEM data framework of FIG. **2**, according to one embodiment.

[0029] FIG. **5** illustrates exemplary IEM data systems associated with the IEM data framework of FIG. **2**, according to one embodiment.

[0030] FIG. **6** illustrates an exemplary IEM data framework having a feedback loop system, according to one embodiment.

[0031] FIG. **7** illustrates an exemplary IEM data framework having a decision support system, according to one embodiment.

[0032] FIG. **8** illustrates an exemplary IEM data framework having auto refill system, according to one embodiment.

[0033] FIG. **9** illustrates an exemplary IEM data framework having patient tools, according to one embodiment.

[0034] FIG. **10** illustrates an exemplary IEM data framework having a behavioral medicine system, according to one embodiment.

[0035] FIG. **11** illustrates an exemplary IEM data framework having an incentive system, according to one embodiment.

[0036] FIG. **12** illustrates an exemplary IEM data framework having a personalized commercial products/services system, according to one embodiment.

[0037] FIG. **13** illustrates an exemplary IEM data framework having an auto billing system, according to one embodiment.

[0038] FIG. **14** illustrates an exemplary IEM data framework having a tracking system, according to one embodiment.

[0039] FIG. **15** illustrates an exemplary IEM data framework having an interdiction system, according to one embodiment.

[0040] FIG. **16** illustrates an exemplary IEM data framework having a subscription system, according to one embodiment.

[0041] FIG. **17** illustrates an exemplary IEM data framework having an ingestible event marker data collection system, according to one embodiment.

[0042] FIG. **18** illustrates an exemplary IEM data framework having an approval system, according to one embodiment.

[0043] FIG. **19** illustrates an exemplary IEM data framework having a forecasting system, according to one embodiment.

[0044] FIG. **20** illustrates an exemplary IEM data framework having a financial system, according to one embodiment.

[0045] FIG. **21** illustrates an exemplary IEM data framework having an ingestible event marker data phone system, according to one embodiment.

[0046] FIG. **22** illustrates an exemplary IEM data framework having a social network system, according to one embodiment.

DETAILED DESCRIPTION

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3.0 IEM Data Framework Method

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5.0 IEM Data Framework System

1.0 Overview

[0075] The ingestible event marker (IEM) data framework provides an integrated, seamless solution to enable the collection, management, distribution, and utilization of IEM data. The versatile IEM data framework facilitates integration and implementation of the IEM data with existing data and utilization of the IEM data with existing systems, i.e., commercial systems. The information and communication systems include discrete systems, cross-configured systems, and hybrid systems.

[0076] Broadly, various aspects of the IEM data framework include a basic complement of core components, e.g., IEM data; a hub; and at least one IEM data system. Any one or a combination of these core components is capable of interoperation, communication, and/or integration with various components of other information/communication systems. The terms "data" and "information" are used interchangeably herein.

[0077] The IEM data include information about an ingestion event, information about a response to the ingestion event, or both. The information about an ingestion event may include, for example, information about the ingestion event of a medication or set of medications. The information about a response to the ingestion event may include, for example, physiologic parameter(s) such as a physiologic status or physiologic change event based on the ingestion event. A physiologic status may be, for example, a heart rate, blood pressure measure, etc., ascertained in close temporal proximity to the time of ingestion of medication (and, therefore, likely to be influenced by or a result of ingestion of the medication.)

[0078] Examples of IEM data include data ingestion time (s) of medication, identification of the type(s) of medication ingested at a particular time, the dosage amounts of medication ingested at a particular time, etc.

[0079] Typically, the IEM data may be generated and/or communicated via an ingestible device such as an ingestible event marker (IEM), which generates and communicates data associated the ingestion event. The IEM may be associated, for example, with a receiver, i.e., a device capable of receiving the IEM data on ingestion and further capable of measuring additional IEM data on response to the ingestion event(s). The IEM and the receiver are discussed in detail hereinafter. In various aspects, the ingestible event data may originate from multiple ingested event markers. In various aspects, the IEM data may be communicated directly from the IEM to a device other than the receiver, e.g., an IEM business system adapted to receive the IEM data directly from the IEM via a communication channel.

[0080] In various aspects, the IEM data may be associated with other data, e.g., combined with data related to events other than an ingestion event or response(s) to an ingestion event. Some examples of other data are data associated with various medical devices and data associated with consumer and personal devices such as intelligent devices/appliances. All are discussed in greater detail hereinafter.

[0081] In various aspects, the IEM data may be associated with an IEM data environment and/or commercial systems.

[0082] In various aspects, the IEM data may be associated with a unique identifier, e.g., sample data reflective of physiologic patterns associated with a particular individual such as heart rate variability, breathing rate, and/or heart rate (ECG) patterns. For example, a portion or all of the IEM data may be compared with a unique identifier generated by or stored on the receiver.

[0083] The hub includes any hardware device, software, and/or communications component(s), as well as systems, subsystems, and combinations of the same which generally function to communicate the IEM data. Communication of the IEM data includes receiving, storing, manipulating, displaying, processing, and/or transmitting the IEM data.

[0084] In various aspects, the hub also functions to communicate, e.g., receive and transmit, non-IEM data. Non-IEM data includes non-IEM physiologic data. One example is cardiac data generated by a separate cardiac-related device such as an implanted pacemaker and communicated to the hub directly or indirectly, e.g., via the receiver.

[0085] Broad categories of hubs include, for example, base stations, personal communication devices, and mobile telephones.

[0086] For example, the hub includes a software application associated with a mobile telephone of a patient. The application and mobile telephone function to receive IEM data from a receiver, which, in turn, receives the IEM data from an ingestible device ingested by the patient. The hub stores, manipulates, and/or forwards the IEM data, alone or in combination with other data, to an IEM data system.

[0087] The IEM data systems include any hardware device, software, and/or communications component, as well as systems and subsystems of the same, which generally function to provide a service or activity related to the IEM data. The IEM data systems, for example, collect, manipulate, calculate, transmit, receive, store, and/or communicate at least a portion of the IEM data.

[0088] Each IEM data system may be built around predefined function(s) or service(s) and may be enabled via the IEM data framework.

[0089] One or more IEM data systems may be integrated, interoperate, intercommunicate or otherwise share or further the collection, management, distribution/dissemination, billing or other activities related to IEM data. One example of an IEM data system is a feedback loop system to refine and optimize IEM data and other data, e.g., medical database data.

[0090] Various aspects of the IEM data framework provide on-demand, accurate and efficient services with respect to provision and utilization of IEM data, while reducing redundancies, errors, and inaccuracies associated with personal event data that are sometimes found in the prior art. Various aspects of the IEM data framework further ensure generation and communication of accurate IEM data in a timely manner.

[0091] Further, the IEM data framework is applicable to any communication environment. Communication environments include any environment having therein, or associated with, data or communication of data.

[0092] Various aspects of the IEM data framework utilize the IEM data, the hub, and one or more IEM data systems to enable useful, secure, and efficient use of the IEM data among multi-profile parties in one or various communication environments.

[0093] FIG. **1** provides a diagrammatic representation of communication environment **100** including an IEM data framework **102**, according to one embodiment. The communication environment **100** may further include, for example, an IEM data environment **104** and one or more commercial systems **106**.

[0094] Communication environment **100** includes any environment having therein, or associated with, data or communication of data. Communication includes any method, act, or vehicle of communication, and/or combinations thereof. For example, communication methods include manual, wired, and wireless, etc. Wireless technologies include radio signals, such as x-rays, ultraviolet light, the visible spectrum, infrared, microwaves, and radio waves, etc. Wireless services include voice and messaging, handheld and other Internet-enabled devices, data networking, etc.

[0095] Vehicles of communication include the Internet, wired channels, wireless channels, communication devices including telephones, computers, wire, radio, optical or other electromagnetic channels, and combinations thereof, including other devices and/or components capable of/associated with communicating data. For example, the communication environments include in-body communications; various devices; various modes of communications such as wireless communications, wired communications, and combinations of the same, etc.

[0096] In-body communications include any communication of data or information via the body, i.e., communication via or associated with inter-body aspects, intra-body aspects, and a combination of the same. For example, inter-body aspects include communications associated with devices designed to attach to a body surface. Intra-body aspects include communications associated with data generated from within the body, e.g., by the body itself or by a device implanted, ingested, or otherwise locatable in, or partially in, the body.

[0097] Communications include and/or may be associated with software, hardware, circuitry, various devices, and combinations thereof.

[0098] The devices include devices associated with IEM data generation, transmission, reception, communication, etc. The devices further include various implantable, ingestible, insertable, and/or attachable devices associated with the human body or other living organisms. The devices further include multimedia devices such as telephones, stereos, audio players, PDA's, handheld devices, and multimedia players.

[0099] Wireless communication modes include any mode of communication between points that utilizes, at least in part, wireless technology including various protocols and combinations of protocols associated with wireless transmission, data, and devices. The points include, for example, wireless devices such as wireless headsets; audio and multimedia devices and equipment, such as audio players and multimedia players; telephones, including mobile telephones and cordless telephones; and computers and computer-related devices and components, such as printers.

[0100] Wired communication modes include any mode of communication between points that utilizes wired technology including various protocols and combinations of protocols associated with wired transmission, data, and devices. The points include, for example, devices such as audio and multimedia devices and equipment, such as audio players and multimedia players; telephones, including mobile telephones and cordless telephones; and computers and computer-related devices and components, such as printers.

[0101] The IEM data framework **102** enables exchange, transmission, receipt, manipulation, management, storage, and other activities and events related to IEM data. Such activities and events may be contained within the IEM data framework **102**, partially integrated with the IEM data framework **102**, or associated with externalities, e.g., activities, systems, components, and the like which are external to the IEM data framework **102**. Externalities include, for example, the IEM data environment **104** and commercial systems **106**, either or both of which may also be integral to, or partially integrated with, the IEM data framework **102**.

[0102] The IEM data environment **104** includes any source of information or data, including remote computer systems, local computer devices, etc. The information or data may comprise IEM data in whole or in part. The

information or data may also be independent of the IEM data, e.g., may be capable of aggregation and/or integration with the IEM data.

[0103] The commercial systems **106** include various existing systems that utilize one or various types of data to accomplish a particular purpose. One example of a commercial system is a computerized pharmacy system utilized in a pharmacy. The computerized pharmacy system may function to automatically, e.g., electronically, receive prescriptions, verify patient and prescription information, verify insurance coverage, process the prescription order, and generate an invoice.

[0104] The IEM data framework **102**, the IEM data environment **104**, and the commercial systems **106** are discussed in greater detail hereinafter.

2.0 IEM Data Framework

[0105] FIG. **2** provides a diagrammatic representation of the IEM data framework **102** of FIG. **1**, according to one embodiment. The IEM data framework **102** includes IEM data **200**, hub **202**, and one or more IEM data systems **204**.

[0106] The IEM data **200** include data associated with an ingestion event, i.e., an act of ingestion. Additionally, the IEM data **200** may include, be included in, or be combined with data from other systems or sources, e.g., medical devices, local or remote computer devices and systems, etc. An example of the IEM data **200** is data having an identification of the type of an ingested medication and the time at which the medication was ingested.

[0107] The hub **202** includes any hardware, software, and/or communications component(s) in any combination/configuration, which generally function to communicate the IEM data **200**. One example includes communicating the IEM data **200** to the IEM data systems **204**. For example, the hub **202** receives the IEM data **200** from an ingested device and forwards the IEM data **200**, alone or in combination with other data from other sources, to an IEM data system **204**.

[0108] The IEM data systems **204** provide discrete services and/or activities related to the IEM data **200**. The discrete services and/or activities include, for example, propagation of information, data, etc., to a particular user, or group of users, via various system component configurations, etc.

[0109] In one example, an auto refill system receives IEM data **200** from the hub **202**. The IEM data **200** include an indication that the last remaining pill of a prescription has been ingested. The auto refill system uses this information to contact a local or remote data resource having refill information, verify the refill information, and automatically transmit a request to a pharmacy system (commercial system) for refill of the prescription.

[0110] 2.1 IEM Data

[0111] The ingestible event marker (IEM) data **200** are associated with at least one of an ingestion event and a response to the ingestion event. The ingestion event may be associated with, for example, data related to and/or gathered during transit through the alimentary system, e.g., oral cavity, pharynx, esophagus, stomach, small intestine, large intestine, anus, etc. Examples of IEM data include an ingestion time, identification of ingested substance, expiration date of an associated medication, dosage of an ingested substance, etc. The information about an ingestion event may include, for example, information about the ingestion event of a medication or set of medications. The information about a response to the ingestion event may include, for example, physiologic parameter(s) such as a physiologic status or physiologic change event based on the ingestion event. A physiologic status may be, for example, a heart rate, blood pressure measure, etc., ascertained in close temporal proximity to the time of ingestion.

[0112] In various aspects, the IEM data **200** typically may be generated via one or more ingestible event markers (IEMs), discussed hereinafter in detail. The generation of IEM data via multiple IEMs ensures comprehensive data reporting, e.g., data generated from multiple ingestion events of multiple IEMs over a time interval, data generated from multiple IEMs ingested at approximately the same time, etc. In this manner, comprehensive IEM data may be provided.

[0113] In various aspects, the IEM data may be communicated to, i.e., received by, a receiver. The receiver may be embodied in various ways, including an implantable device, a semi-implantable device such as a subcutaneous device, and an externally-applied device such as a personal signal receiver. One example of a personal signal receiver is a "patch" receiver which may be removably affixed to the individual's person, apparel, etc.

[0114] In various aspects, the IEM data **200** can be associated with other data, e.g., a personal event not associated with an ingestion event or a response to an ingestion event. A personal event includes any parameter or circumstance associated with a person, e.g., any event associated with ingestion, inhalation, injection, implantation, insertion, and/or imbibing of a device, substance, liquid, etc. A personal event further includes any event associated with personal data, e.g., a physiologic parameter such weight.

[0115] In various aspects, the IEM data may be associated with a unique identifier, e.g., heart rate variability, breathing rate, and/or heart rate (ECG) patterns associated with a particular individual. The unique identifier may be variously embodied. One example is a personal identifier assigned to an individual, e.g., an alphanumeric code, etc. Another example is a unique identifier reflective of an individual trait, such as a physiologic pattern.

[0116] To illustrate, a patient may ingest an IEM (discussed hereinafter) integrated with medication. The IEM may communicate IEM data to a receiver such as a patch receiver (discussed hereinafter). The data may include, for example, a unique identifier which may be compared to data associated with the receiver for validation purposes.

[0117] In one scenario, the IEMs associated with medication prescribed for a particular patient may each be encoded and deployed with corresponding unique identifiers. The unique identifier may be, for example, a predetermined physiologic data sample associated the particular patient. Various physiologic data samples include a data sample reflective of the particular patient's heart rate variability, a data sample reflective of the particular patient's breathing rate, a data sample reflective of the particular patients heart rate (ECG) patterns, etc.

[0118] When the receiver is affixed or otherwise associated with an individual, programming logic associated with the receiver may receive actual data samples of the individual, e.g., from data sources such as heart devices, etc. The receiver may communicate the actual data samples received from the data sources and the unique identifier(s) received from the IEM(s) to a computer-related device, e.g., a server,

which may compare the actual data samples of the individual with the unique identifier to verify that the medication was actually ingested by the particular patient for whom it was prescribed. In various aspects, predetermined actions based on the verification outcome may be taken, e.g., alerts may be sent to a device associated with the prescribing physician, etc.

[0119] 2.1.1 IEM Data Environment

[0120] In various embodiments, IEM data **200** are generated, received, gathered, etc., from one or a variety of sources and comprise various structures, content, types, etc. The IEM data environment includes at least one of an IEM data source device, products, events, patient specific parameters, IEM data algorithms, and storage repositories. The sources include, for example, various devices, storage repositories, and systems capable of generating, identifying, gathering or otherwise producing data related to ingestion, the ingestion environment, e.g., the alimentary system of a human subject or non-human subject and/or other personal events. The types include, for example, raw data, processed data, aggregated data, combined data, data from various sources, etc. The processed data include, for example, data processed according to a variety of methods, e.g., algorithms such as IEM data algorithms discussed below.

[0121] FIG. **3** illustrates IEM data environment **104** associated with the IEM data framework **102** of FIG. **2**, according to one embodiment. The IEM data environment **104** includes, for example, IEM data source devices **300**, products **302**, events **304**, patient specific parameters **306**, IEM data algorithms **308**, storage repositories **310**, and other sources **312**.

[0122] 2.1.1.1 IEM Data Source Devices

[0123] The ingestible event marker (IEM) data source devices **300** include, for example, devices capable of gathering, collecting, generating, receiving, storing and/or transmitting, etc., IEM data. One example of such a device is a microchip capable of or otherwise enabling or facilitating the collection, generation, receipt, transmission, etc., of data. Such a microchip may be integrated or associated with the IEM data source devices **300**. The IEM data source devices **300** may be embodied, for example, as ingestible devices **300***a*, receivers **300***b*, and/or health devices **300***c*.

[0124] In various aspects, IEM data may be related to various devices. For example, a device may be an ingestible device, an inhalable device, an injectable device, an implantable device, an insertable device, and an imbibable device. The foregoing may be embodied, for example, as a microchip alone or in combination with other structural components, each capable of at least one of ingestion, inhalation, injection, implantation, insertion, and imbibement by a human body or a non-human body.

[0125] The ingestible device may comprise, for example, a microchip. The microchip may be independently deployed. The microchip may also be attached to, embedded in, or otherwise integrated with a medication, e.g., a pill (refer to IEM system, infra).

[0126] The inhalable device may comprise, for example, a microchip. The microchip may be independently deployed. The microchip may also be attached to, embedded in, or otherwise integrated with a device. The inhalable device is capable of ascertaining parameter(s) associated with inhalation, e.g., measuring or tallying doses of an inhalant. The inhalable device may also comprise, for example, an inhalable microchip used to ascertain parameter(s), e.g., inhalation time, identify an inhaled substance, etc.

[0127] The injectable device may comprise, for example, a microchip. The microchip may be independently deployed. The microchip may also be attached to, embedded in, or otherwise integrated with a device. The injectable device is capable of ascertaining parameter(s) associated with injection, e.g., time of injection, identification of an injected substance, etc. In various aspects, the injectable device is capable of injection into a human body or a non-human body, e.g., injection into the circulatory system of a human body.

[0128] The implantable device may comprise, for example, a microchip. The microchip may be independently deployed. The microchip may also be attached to, embedded in, or otherwise integrated with a device. The implantable device is capable of ascertaining parameter(s) associated with implantation, e.g., time of implantation, physiologic parameters such as heart rate, EKG data, activity management data, temperature, galvanic skin response data, respiratory data, fluid status data, heart rate variability, etc.

[0129] In one aspect, the implantable device is embodied as an implantable receiver, supra, for receiving various data. The implantable receiver may also process, store, transmit, etc. the data. Various other implantable devices include, for example, heart monitors and the like having a microchip to ascertain parameter(s), e.g., heart rate, heart pressure, etc.

[0130] The insertable device may comprise, for example, a microchip. The microchip may be independently deployed. The microchip may also be attached to, embedded in, or otherwise integrated with a device. The insertable device is capable of ascertaining parameter(s) associated with insertion, e.g., time of insertion, physiologic parameters such environmental content/fluid identification, etc. In one aspect, the insertable device is embodied as a microchip mechanically associated with a suppository for rectal insertion, vaginal insertion, etc.

[0131] The imbibable device may comprise, for example, a microchip. The microchip may be independently deployed. The microchip may also be attached to, embedded in, or otherwise integrated with a substance, e.g., a potable solution or fluid such as a beverage, etc. The imbibable device is capable of ascertaining parameter(s) associated with imbibing, e.g., time of drinking, physiologic parameters such as environmental content/fluid identification, etc. In one aspect, the imbibable device is embodied as a microchip and imbibed together with a beverage. The beverage may aid in swallowing, may be used as a medication, etc.

[0132] Further, the IEM data may be associated with administration of a therapeutic agent, etc. For example, administration includes, but is not limited to, parenteral administration, i.e., administration in a manner other than through the alimentary system, such as by intravenous or intramuscular injection or inhalation.

[0133] In some aspects, the devices are capable of ingestion, i.e., entry into the alimentary system of a human body or a non-human; inhalation (either the device or a substance associated with the device, e.g., a nasal inhalant). In various aspects the devices are capable of injection, insertion, implantation and/or imbibing, etc., into/by a human body or a non-human body.

[0134] The ingestible devices **300***a* gather/collect/generate IEM data via various methods, e.g., ingestion timing, contact with alimentary system substances, sampling, etc.

Further, various ingestible event marker data source devices **300** communicate the IEM data via various methods, e.g., wireless methods, conductive methods via body tissue, etc. The following are examples of the ingestible devices **300***a*.

[0135] A pharma-informatics system described in PCT/US2006/016370, filed Apr. 28, 2006, includes compositions, systems and methods that allow for the detection of the actual physical delivery of a pharmaceutical agent to a body are provided. Embodiments of the compositions include an identifier and an active agent.

[0136] An IEM system described in PCT/US2008/52845, filed Feb. 1, 2008, includes an ingestible event marker (IEM) and a personal signal receiver. Aspects of the IEM include an identifier, which may or may not be present in a physiologically acceptable carrier. The identifier is characterized by being activated upon contact with a target internal physiological site of a body, such as digestive tract internal target site. The personal signal receiver is configured to be associated with a physiological location, e.g., inside of or on the body, and to receive a signal of the IEM. During use, the IEM broadcasts a signal which is received by the personal signal receiver.

[0137] The IEM data associated with the IEM system include personal data, e.g., physiologic data generated by the IEM. Examples are derived metrics, e.g., processed physical data to derive various metrics such as time of ingestion data; combined metrics, e.g., derived metrics combined with other derived metric data such as time of ingestion data combined with data identifying the ingested substance; and IEM data, e.g., derived metrics and/or combined metrics aggregated with various physiologic data such as time of ingestion data combined with data identifying the ingested substance and physiologic data such as ECG data, temperature, etc.

[0138] A controlled activation ingestible identifier described in PCT/US07/82563, filed Oct. 17, 2007, includes ingestible compositions such as pharma-informatics enabled compositions. The controlled activation ingestible identifiers include a controlled activation element that provides for activation of the identifier in response to the presence of a predetermined stimulus at a target site of interest.

[0139] A life cycle pharma informatics system described in U.S. Patent Applications Ser. No. 61/034,085, filed Mar. 5, 2008 includes RFID and conductive communications technology combined with medication and/or medication packaging such that the medication can be tracked for the duration of its existence. The system further allows in-body data transmissions while addressing the potential privacy and signal degradation concerns associated with RFID technology.

[0140] The IEM data receivers **300***b* include devices capable of receipt of IEM data **200**. Receipt may be, for example, via wireless or wired channels, etc. The IEM data receiver **300***b* may also transmit or otherwise forward data. In various aspects, the IEM data receiver **300***b* may perform, facilitate, or enable various other functionalities related to the IEM data **200** and/or other data. In various aspects, the IEM data receiver **300***b* may be attachable, implantable, semi-implantable or otherwise associated with a human body or a non-human body.

[0141] The IEM data receiver **300***b* include personal signal receivers such as patch receivers, e.g., removably attachable externally to a human body or a non-human body; subcutaneous devices; implantable devices; external devices, i.e., devices which are not designed for attachment or other permanent or semi-permanent contact with the body, e.g., a mobile telephone. The following are examples of the IEM data receiver **300***b*.

[0142] The IEM system, PCT/US2008/52845, supra, includes an ingestible event marker (IEM) and/or a personal signal receiver.

[0143] An active signal processing personal health signal receiver described in PCT/US07/24225, filed Nov. 19, 2007, includes a receiver associated with a body, e.g., located inside or within close proximity to a body, configured to receive and decode a signal from an in vivo transmitter which is located inside the body.

[0144] The health devices **300***c* include multiple devices (and methods associated with the devices) associated with the IEM data **200**. The health devices **300***c*, for example, may gather, collect, aggregate, store, transmit, receive, or otherwise communicate data, including the IEM data **200**.

[0145] Communication may be, for example, via wireless or wired channels, etc. The IEM data receiver may also transmit or otherwise forward data. In various aspects, the IEM data receiver **300***b* may perform, facilitate, or enable various other functions related to the IEM data and/or other data. Examples include functions to store data, process data, etc.

[0146] In various aspects, the health device **300***c* may be attachable, implantable, semi-implantable or otherwise associated with a human body or a non-human body. For example, "intelligent" devices such as intelligent scales, intelligent blood pressure cuffs, intelligent refrigerators, etc., may be integrated in various configurations. As used herein, the term "intelligent devices" refers to one or more devices capable of generating and/or communicating data, e.g., wirelessly transmitted data, via a communication channel to a destination.

[0147] 2.1.1.2 Products

[0148] IEM data **200** also includes IEM data related to products **302**. The products **302** include, for example, an ingestible device/pharmaceutical product **302***a*. One example of an ingestible device/pharmaceutical product **302***a* is an IEM mechanically associated with medication. The IEM may be mechanically associated with the medication in various ways, including externally affixed to the medication, partially integrated with the medication, and wholly integrated with the medication.

[0149] The IEM may be affixed via various means, e.g., with various adhesive or formulated substances. The IEM may be associated with the medication at various phases, e.g., during a medication manufacturing process, at various points in time after a medication manufacturing process, etc.

[0150] 2.1.1.3 Events

[0151] IEM data **200** further includes data related to events **304**, e.g., personal events, event parameters, etc. Further examples include time of ingestion of a medication, dosage and identity of medication taken at time of ingestion, etc. Events may include physiologic events, e.g., respiration rate; environmental events, e.g., time of day; usage events, e.g., ingestion of a medication, use of a cardiac resuscitation device, etc.

[0152] 2.1.1.4 Patient Specific Parameters

[0153] IEM data **200** still further includes data related to patient specific parameters **306**, e.g., individualized patient data **306***a* pertaining to an individual patient and multiple patient data **306***b* pertaining to multiple patients. Examples of patient specific parameters include physiologic data, etc.

Multiple patient data include aggregated patient data, patient population data, e.g., combined patient data which includes various predetermined aspects of data regarding at least one patient and excludes data tending to identify a particular patient or an aspect in which the patient has a privacy interest, e.g., name, age, diagnosis and/or other data which the patient wishes to retain as confidential and/or undisclosed to the public.

[0154] 2.1.1.5 IEM Data Algorithms

[0155] IEM data **200** also includes data related to IEM data algorithms **308**, e.g., raw data, processed data, or a combination of the same, which undergo processing. In one example, the IEM data **200** have one or more algorithms applied thereto, with processed data as an output. The data, for example, includes individualized patient data **306***a* and multiple patient data **306***b*, e.g., patient population data.

[0156] The IEM data algorithms may be related to aspects such as data processing associated with the IEM data **200** generated by one or more ingestible devices, e.g., an IEM system.

[0157] With respect to IEM data processing associated with an ingestible device, aspects include, for example, transmission of the IEM data **200**, IEM data processing associated with a receiver, and IEM data post-processing aspects.

[0158] Transmission aspects of IEM data and algorithms may include, for example, modulation schemes, coding, and error code aspects.

[0159] The transmission aspects include, for example, analog, digital, spread spectrum, combinatorial, and contention avoidance.

[0160] The analog transmission aspects include, for example, amplitude modulation, single sideband modulation, frequency modulation, phase modulation, quadrature amplitude modulation, and space modulation methods, etc.

[0161] The digital transmission aspects include on/off keying, frequency-shift keying, amplitude-shift keying, phase-shift keying, e.g., binary phase-shift keying, quadrature phase-shift keying, higher order and differential encoded, quadrature amplitude modulation, minimum shift keying, continuous phase modulation, pulse-position modulation, trellis coded modulation, and orthogonal frequency-division multiplexing.

[0162] The spread spectrum transmission aspects include, for example, frequency hopping spread-spectrum and direct-sequence spread spectrum.

[0163] The combinatorial transmission aspects include, for example, binary phase shift-keying with carrier frequency modulation.

[0164] The contention avoidance transmission aspects include, for example, duty-cycle modulation and carrier frequency modulation.

[0165] The coding aspects include, for example, wake-up schemes, preamble schemes, data packet schemes, and error code schemes.

[0166] The wake-up schemes include, for example, multi-tone schemes and chirp schemes.

[0167] The preamble schemes include, for example, unique identifier for packet start schemes.

[0168] The data packet schemes include, for example, data related to pill type, pill expiration, manufacturer, lot number, amount, prescribing physician, pharmacy, etc.

[0169] The error code schemes include, for example, repetition schemes, parity schemes, checksums, cyclic redundancy checks, hamming distance schemes, and forward error correction schemes, e.g., Reed-Solomon codes, binary Golay codes, convolutional codes, turbo codes, etc.

[0170] With respect to IEM data processing and the receiver, considerations may be given to, for example, position, energy conservation schemes, carrier identification, decoding and error correcting.

[0171] The position of the receiver includes, for example, the stomach, the side and the xiphoid.

[0172] The energy conservation schemes include schemes for a periodic wake-up, e.g., to sense IEM wake-up such that energy, e.g., battery resources, is conserved during non-awake periods.

[0173] The carrier identification aspects include, for example, Fourier transform analysis, e.g., fast Fourier transform and discrete Fourier transform, phase locked loop, filter bank, match filter, and combinatorial such as use of previous knowledge about frequency to tune-in.

[0174] The decoding aspects and error correcting aspects include, for example, the above-iterated aspects.

[0175] With respect to IEM data post-processing, aspects include, for example, pill detection, e.g., multiplicity of identification and count in time aspects, adherence metrics, etc.

[0176] With respect to IEM data processing associated with physiologic parameter metrics, aspects include, for example, electrocardiogram (EKG or ECG), impedance, acceleration, optical, pressure, temperature, sound, biochemical/biological, weight, position, derived electromyography (EMG), and electroencephalography (EEG).

[0177] IEM data processing related to EKGs includes, for example, compression data, e.g., wavelet and ICA/PCA, R-wave detection such as Hamilton-Tompkins, etc., heart-rate variability, e.g., SDNN, standard deviation in a 24 hour period, standard deviation of consecutive five minute periods, foot print heart rate versus standard heart rate, distribution-based histogram, etc., arrhythmia, and respiration, e.g., principal axis modulation.

[0178] IEM data processing related to impedance includes, for example, respiration, fluid status, Galvanic skin response, blood flow, etc.

[0179] IEM data processing related to acceleration, includes, for example, direct acceleration, which includes total activity and derived acceleration, which further includes activity type.

[0180] IEM data processing related to optical includes, for example, hematocrit, O2 saturation, pulse oximetry, etc.

[0181] IEM data processing related to temperature includes, for example, body temperature, heat flux, etc.

[0182] IEM data processing related to sound includes, for example, heart sounds, valvular events, etc.

[0183] IEM data processing related to biochemical/biological includes, for example, lactose, glucose, antibody, biomarker, bacterial, osmolarity, etc.

[0184] IEM data processing related to derived data include, for example, sleep, total energy, etc.

[0185] 2.1.1.6 Storage Repositories

[0186] Ingestible event marker data also includes data related to storage repositories **310**, i.e., databases and/or other storage implementations that temporarily and/or permanently retain, store, etc., data related to IEM data, including data to be combined or aggregated with ingestible event marker data.

[0187] Storage may be in any form or format, as is known or will be known in the future. In various aspects, the storage repositories **310** may be independently embodied and/or may be partially or wholly integrated with computer-related system(s). The storage repositories **310**, for example, may interoperate or otherwise be associated with various computer systems, software, hardware, communication components, etc. For example, the storage repositories **310**, may be part of a medical office computer system and may contain IEM data **200** related to a particular's patient's medication regimen. At various times, e.g., scheduled or ad hoc, various IEM data **200** embodied as medical data may be communicated to/from the storage repositories **310** and/or from/to various points/components.

[0188] In another illustration, methods, systems and compositions that allow for treating a patient according to a patient customized therapeutic regimen are described in PCT/US2007/1068, filed May 2, 2007, which include obtaining dosage administration information from a patient and using the same to tailor a therapeutic regimen for the patient, as well as preparing and forwarding to the patient physical pharmaceutical dosages based on the customized therapeutic regimen. The dosage administration information from the patient may be stored, for example, on the database **306**. The IEM data **200** containing information about the ingestion time of a particular medication can be combined with the dosage administration information to customize the therapeutic regimen.

[0189] 2.1.1.7 Other IEM Data Sources

[0190] In various aspects, various other IEM data sources **312** are/can be included. Further, it is noted that data and/or IEM data **200** from multiple sources can be aggregated, integrated, refined, etc. via a variety of methods. To illustrate, IEM data **200** such as ingestion data related to ingestion of a medication are generated from an IEM data source device **300** such as the IEM system. The ingestion data are wirelessly transmitted to an IEM receiver.

[0191] Concurrently or in an alternative time period, physiologic data such as cardiac parameters are generated by a health device **300***c* such as the system for monitoring and treating hemodynamic parameters, supra, is generated and wirelessly transmitted to the IEM data receiver **300***b*. The IEM data **200** and the cardiac physiologic data are aggregated for onward communication to an IEM data system such as an auto refill system.

[0192] To illustrate, cardiac data is derived via various methods and systems. One example is continuous field tomography, e.g., electrical tomography (ET). One continuous field tomography method is described in the U.S. Patent Application Ser. No. 60/797,403, filed May 2, 2006. The cardiac data includes cardiac-related parameters, as well as clinical data for clinical applications. Using ET, various cardiac parameters are measured, such as stroke volume, ejection fraction, dP/dt(max), strain rate(max), peak systolic mitral annular velocity, end systolic volume, end diastolic volume, and QRS length, etc. The cardiac measurements may be used to derive or infer various performance and wellness diagnostics/inferences. For example, an ejection fraction parameter may be used as a basis to predict ventricular synchrony performance.

[0193] The metrics generated from the continuous field tomography include, for example, velocity, acceleration, and displacement.

[0194] The clinical data derived from the metrics include, for example, left ventricle stiffness as well as ET proxies for other physiologic parameters such as ejection fraction (EF) and dP/dt.

[0195] In various aspects, the clinical data may be combined with the IEM data to provide additional information. The information may be useful, for example, in various diagnostic and analytical pursuits. Comprehensive patient-related data displays having clinical data and IEM data are described in the U.S. Patent Application Ser. No. 61/076,577, filed Jun. 27, 2008, wherein various ET physiologic parameters and derivations such as EF and ventricle stiffness are displayed together with IEM data such as medication ingestion time. From such a display, the efficacy of the medication therapy may be gauged.

[0196] 2.2 Hub

[0197] The hub **202** includes any hardware device, software, and/or communications component(s), as well as systems, subsystems, and combinations of the same which generally function to communicate the IEM data **200**, including receiving, storing, manipulating, displaying, processing, and/or transmitting the IEM data **200**.

[0198] In various aspects, the hub **202** receives, generates, communicates, and/or transmits, the IEM data **200**, alone or in combination with other data, i.e., non-IEM data from various sources. Non-IEM data includes non-IEM physiologic data. Examples of non-IEM data include heart rate, heart rate variability, respiration, physical activity level, wake patterns, temperature, etc.

[0199] Communication of the IEM data **200** to and from the hub **202** includes any transmission means or carriers, and combinations thereof, including wireless, wired, RF, conductive, etc. as is known in the art or as may become available in the future.

[0200] FIG. **4** illustrates the hub **202** associated with the IEM data framework **102** of FIG. **2**, according to one embodiment. The hub **202** comprises various categories of devices, e.g., personal communication devices, base stations, and mobile telephones.

[0201] Personal communication devices include, for example, devices having communication and computer functionality and typically intended for individual use, e.g., mobile computers, sometimes referred to as "handheld devices".

[0202] Base stations comprise any device or appliance capable of receiving data such as IEM data. Examples include computers, such as desktop computers and laptop computers, and intelligent devices/appliances.

[0203] Intelligent devices/appliances include consumer and home devices and appliances that are capable of receipt of data such as IEM data. Intelligent devices/appliances may also perform other data-related functions, e.g., transmit, display, store, and/or process data. Examples of intelligent devices/appliances include devices and appliances having refrigerators, weight scales, toilets, televisions, door frame activity monitors, bedside monitors, bed scales. Such devices and appliances may include additional functionality such as sensing or monitoring various physiologic parameters, e.g., weight, heart rate, etc.

[0204] Mobile telephones include telephonic communication devices associated with various mobile technologies, e.g., cellular networks.

[0205] In one aspect, the hub **202** includes an IEM data receiver embodied, for example, as a receiver such as a patch

receiver **400**; a personal communication devices such as a handheld device **402**; a base station **404**; and a mobile telephone **406**.

[0206] The patch receiver **400** includes, for example, devices capable of at least receiving data, signals, etc. Patch receivers **400** may be attachable, e.g., permanently or removably attachable externally to a human body or a non-human body. For example, the patch receiver **400** may include a receiver and an adhesive layer to provide for attachment to and removal from a region of skin. Alternatively, the patch receiver **400** may be implantable or semi-implantable, e.g., subcutaneous implantation. One such removably attachable patch receiver **400** is the personal signal receiver of the IEM system described in PCT/US2008/52845, supra.

[0207] The handheld device **402**, also referred to as a "mobile computer", includes, for example, computing devices having computer-related functionality, e.g., typically having a display screen with touch input functionality, a miniature keyboard, etc. Types of handheld devices include, for example, a personal digital assistant (PDA) having the input and output combined into a touch-screen interface; and enterprise digital assistants offering integrated data capture devices like bar code, radio frequency identification (RFID), and smart card readers, etc.

[0208] In various aspects, the handheld device **402** includes software, e.g., a software agent/application, associated with the IEM data **200**. In various embodiments of the handheld device **402**, the software is preconfigured, i.e., configurable by the manufacturer/retailer; configurable by the consumer, i.e., downloadable from a website; or a combination of the same.

[0209] One example of software is an auto refill application related to or integrated with an auto refill system to facilitate automated prescription refill functions.

[0210] The base station **404** includes systems, subsystems, devices, and/or components that receive, transmit, and/or relay the IEM data **200**. In various aspects, the base station communicably interoperates with a receiver such as the patch receiver **400** and a communications network such as the Internet. Examples of base stations **404** are computers, e.g., servers, personal computers, desktop computers, laptop computers, intelligent devices/appliances, etc., as heretofore discussed.

[0211] In various aspects, the base station **404** may be embodied as an integrated unit or as distributed components, e.g., a desktop computer and a mobile telephone in communication with one another and in communication with a patch receiver and the Internet.

[0212] In some aspects, the base station **404** includes the functionality to wirelessly receive and/or wirelessly transmit data, e.g., IEM data **200** received from and transmitted to the patch receiver **400** and the Internet.

[0213] Further, in various aspects, the base station **404** may incorporate and/or be associated with, e.g., communicate with, various devices. Such devices may generate, receive, and/or communicate data, e.g., IEM data **200**. The devices include, for example, clock radios, intelligent pill dispensers, pill managers, e.g., devices capable of receiving various substances and producing a combined substance, dose(s) of substances, etc., pharmaceutical compounding devices, "intelligent" devices such as scales, blood pressure measurement devices, exercise equipment, e.g., tread mills. Further examples include body weight sensors, motion sensors, position sensors, e.g., bed sensors, chair sensors, portals in doorways, refrigerator and food devices, bathroom facilities devices, etc.

[0214] The mobile telephone **406** includes, for example, devices such as a short-range, portable electronic device used for mobile voice or data communication over a network of specialized cell site base stations. The mobile telephone **406** is sometimes known as or referred to as "mobile", "wireless", "cellular phone", "cell phone", or "hand phone (HP)".

[0215] In addition to the standard voice function of a telephone, various embodiments of mobile telephones may support many additional services and accessories such as short message service (SMS) for text messaging, email, packet switching for access to the Internet, java gaming, Bluetooth (short range data/voice communications), infrared, camera with video recorder, and MMS for sending and receiving photos and video. Some embodiments of mobile telephones connect to a cellular network of base stations (cell sites), which is, in turn, interconnected to the public switched telephone network (PSTN) or satellite communications in the case of satellite phones. Various embodiments of mobile telephones can connect to the Internet, at least a portion of which can be navigated using the mobile telephones.

[0216] In various aspects, the mobile telephone **406** includes software, e.g., a software agent/application, associated with the IEM data **200**. One example is an auto refill application related to or integrated with an auto refill system to facilitate automated prescription refill functions. In various embodiments of the mobile telephone **406**, the software is preconfigured, i.e., configurable by the manufacturer/retailer; configurable by the consumer, i.e., downloadable from a website; or a combination of the same.

[0217] Further, various embodiments of the hub ensure privacy requirements via predetermined methods, e.g., an IEM data source device **300** ingested by an individual transmits sensitive IEM data **200** via body tissues to an IEM data receiver **302** embodied in a patch receiver **400** removably attached to the individual's body. Signals associated with the sensitive IEM data **200** remain undetectable beyond the individual's body. Once received by the patch receiver **400**, various computing components of the patch receiver **400** cleanse and/or encrypt the IEM data **200** for onward secure transmission. In this manner, breaches of sensitive data transmissions and/or unauthorized access to the sensitive data are avoided.

[0218] Further, various aspects of the hub include combinations of devices. One such combination is an IEM data receiver **300***b* such as the patch receiver **400** in communication with the handheld device **402** or the mobile telephone **406**. Thus, for example, the patch receiver **400** wirelessly transmits IEM data **200** to the mobile telephone **406** having a receiver and a software agent available thereon. The receiver of the mobile telephone **406** receives the IEM data **200**. A software agent, e.g., an application, processes the ingested reported data **200** and displays various information related to the IEM data **200** via, for example, a customized graphical user interface (GUI). In some aspects, the software agent generates displays with a predetermined "look and feel", i.e., recognizable to a user as belonging to a predetermined group of software programs, GUIs, source devices, communities, etc.

[0219] To illustrate the foregoing, the IEM data **200** may include data about an ingested medication. Once received by the mobile telephone **406**, the software agent may compare the data about the medication to a predetermined medication regimen. Upon verification that the proper medication has been ingested at the proper time, the software disables an audible alarm scheduled to alert the individual to take the (already ingested) medication, thus averting an unnecessary reminder and removing the annoyance associated therewith. The software agent, via the GUI, displays a standard message to the individual notifying of the medication ingested and the time of the next dosage.

[0220] Additionally, the software agent may include functionality to generate or facilitate a financial transaction. In one example, upon occurrence of a certain event, such as verification that the proper medication has been ingested at the proper time, the software agent generates a predetermined charge for the ingested medication, the verification service, or both. The charge is transmitted to a financial system, e.g., the patient's cell phone transmits the charge via an IEM data system to a computer system associated with the patient's financial institution where the charge is automatically applied against a financial account of the patient.

[0221] In various other aspects, the transaction model may be based on various parameters. In one example, a transaction is associated with a time based model wherein use of a product or service is charged according to the length of time the product or service is used. In another example, a transaction is associated with a measured value delivery, wherein the value of the product or service is metered, measured, or otherwise valued and charged according to the ascertained value at predetermined time intervals. In still another example, a transaction is associated with therapy delivery, i.e., delivery of a therapeutic substance, event, service, etc. Examples of therapeutic substances include medication. Examples of therapeutic events include cardiac defibrillation acts and cardiac resynchronization acts. Examples of therapeutic services include administration of therapeutics, therapeutic consultations, etc.

[0222] 2.3 IEM Data Systems

[0223] The IEM data systems **204** include any hardware component, software component, and/or communications component, as well as networks, systems, and subsystems of the same, which generally function to provide a service, function, activity, etc. related to the IEM data **200**. The IEM data systems, for example, collect, manipulate, calculate, transmit, receive, store, and/or otherwise communicate at least a portion of the IEM data.

[0224] Each IEM data system is built around a predefined business function or service and is enabled via the IEM data framework. One or more IEM data systems may be integrated, interoperate, intercommunicate or otherwise share or further the collection, management, distribution/dissemination, billing and/or other activities related to IEM data.

[0225] Further, one or more IEM data systems may be associated with one or more commercial systems. For example, one or more IEM data systems may be integrated with, interoperate with, and/or intercommunicate with one or more commercial systems. One or more IEM data systems may otherwise share or further the IEM data related activities with one or more commercial systems.

[0226] The IEM data systems **204** include at least one component, e.g., hardware device, software, and/or communications component, which generally function to provide a service or activity related to the IEM data **200**, e.g., a computer to receive IEM data **200** from the hub **202** and display the IEM data **200** in conjunction with other information.

[0227] Examples of components include a computer, a receiver, a transmitter, an application, a software module, a data storage medium, a processor, a memory component, a personal communication device, software, a communication link, and a handheld device. It is noted that two or more IEM data systems **204** can cooperatively or independently use one or more of the same components. For example, an auto refill system and an approval system can each access a data storage medium having IEM data related to patients and prescriptions and can each utilize the IEM data for predetermined purpose(s).

[0228] FIG. **5** illustrates exemplary IEM data systems **204** associated with the IEM data framework of FIG. **2**, according to one embodiment. The exemplary IEM data systems **204** include, for example, feedback loop systems **204***a*, decision support systems **204***b*, auto refill systems **204***c*, patient tools **204***d*, behavioral medicine systems **204***e*, incentive systems **204***f*, personalized commercial products/services **204***g*, auto billing systems **204***h*, tracking systems **204***i*, interdiction systems **204***j*, subscription systems **204***k*, IEM data collections **204***l*, approval systems **204***m*, forecasting systems **204***n*, financial systems **204***o*, an IEM data phone system **204***p*, and social networks **204***q*.

[0229] 2.3.1 Feedback Loop Systems

[0230] Feedback loop systems aggregate various sources of data, e.g., IEM data, analyze the aggregated data, and/or provide feedback information to multiple profile recipients based on the aggregation/analysis.

[0231] FIG. **6** illustrates an exemplary IEM data framework **102** including a feedback loop system **204***a*, according to one embodiment. The feedback loop system **204***a* includes, for example, server **500** having application **502** and database **504**. The IEM data framework **102** further includes IEM data **200** and the hub, embodied here as the mobile telephone **406**. In various aspects, the feedback loop system **204***a* may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

[0232] In one scenario, a patient **506** ingests medication having an ingestible device integrated therein. The ingestible device generates IEM data **200** in the form of medication identification and time of ingestion information. The ingestible device transmits the information to a receiver. The receiver, in turn, communicates the information to the hub **202** embodied as a mobile telephone **406** associated with the patient **506**.

[0233] A software agent resident on the mobile telephone **406** aggregates the received medication identification and time of ingestion information with the blood pressure measurement information and forwards the aggregated data to the feedback loop system **204***a*. The feedback loop system **204***a*, having server **500**, software **502**, and database **504**, receives the aggregated data from the mobile telephone **406** and, via the software **502**, compares the aggregated data to patient information in the database **504** to determine if the patient **506** took the most recent dose of medication in a timely manner, if the patient **506** has consistently taken the medication in a timely manner, and if the blood pressure measurement coincides with an acceptable range of blood pressure measurements.

[0234] Based on an analysis of the data, the feedback loop system **204***a* generates additional IEM data **200** in the form of a decision on patient adherence and a decision on treatment efficacy. The IEM data **200** decisions are stored in database **504** for future reference and forwarded to a commercial system such as a healthcare system **106***a* associated with a medical center computer system and having patient data such as physician's medication instructions, etc.

[0235] The healthcare system **106***a* facilitates automatic processing and feedback, enables accessibility to the IEM data **200**, e.g., by a healthcare provider, enables data input, e.g., healthcare instructions by the healthcare provider, etc.

[0236] For example, the healthcare system **106***a* compares the decision data received from the feedback loop system **106***a* with stored healthcare providers instructions, e.g., medication regimen adherence is satisfactory and no action is needed at this time; medication regimen adherence is not satisfactory and action is needed at this time; medication regimen is satisfactory but action is needed at this time, e.g., titration is needed, etc., and generates the comparison result data for review by the healthcare provider.

[0237] The healthcare provider utilizes the information to advantageously adjust patient treatment parameters, e.g., prescription and dosage requirements. The healthcare provider inputs data based on the comparison results, e.g., the adjusted treatment parameters. The input data are processed by the healthcare system **106***a* and forwarded to the feedback loop system **204***a*. The feedback loop system **204***a* receives the feedback loop data, reconciles the feedback loop data with the patient information resident in the database **504**, and forwards the notification to the mobile telephone **406** of the patient **506**.

[0238] In various aspects, the feedback loop system **204***a* and/or the healthcare system **106***a* interoperate, e.g., communicate with at least one other IEM data system **204** and/or commercial system **106**.

[0239] To continue the foregoing illustration, in addition to forwarding the adjusted medication regimen instructions to the patient's mobile telephone **406**, either the feedback loop system **204***a* or the healthcare system **106***a* forwards the adjusted medication regimen in the form of a prescription to a commercial system such as a pharmacy system **106***b* for refill. The pharmacy system **106***b* fills the prescription and communicates a message to the feedback loop system **204***a* notifying of the same. The feedback loop system **204***a* updates the patient's data in database **504** to reflect the new prescription and fulfillment of the prescription, and communicates the notification to the patient's mobile telephone **406**.

[0240] 2.3.2 Decision Support Systems

[0241] Decision support systems, e.g., personal wellness systems, may generate, store, provide data, e.g., IEM data, which may be used to inform and support decisions, e.g., stakeholders' decisions. In one example, multiple instances of individualized ingestible event marker data and physiologic data are gathered and combined into anonymized patient population data. Pharmaceutical research and development groups, universities, etc., utilize the data for various purposes, e.g., information to formulate new product lines, adjust existing therapies, etc. The data may be accessed, for example, by subscription to population data feeds, access to the database, etc.

[0242] FIG. **7** illustrates an exemplary IEM data framework **102** having a decision support system **204***b*, according to one embodiment. The IEM data framework **102** further includes IEM data **200** and the hub **202**, shown here embodied as the mobile telephone **406**. In various aspects, the feedback loop system **204***a* may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

[0243] In one scenario, IEM data, e.g., IEM data **200***a* and IEM data **200***b*, related to multiple individuals, e.g., patient **506***a* and patient **506***b*, respectively, are communicated via the hubs, e.g., mobile telephone **406***a* and mobile telephone **406***b*, respectively, to the decision support system **204***b* comprising, for example, server **500**, software **502**, and database **504**. The IEM data **200***a* and **200***b* may be encrypted. The decision support system **204***b* processes and stores the received data. For example, software **502** anonymizes the patient data, i.e., removes all aspects of the data tending to identify an individual and removes, according to a predetermined scheme, all aspects of the data designated as private, sensitive, confidential in nature, etc. The software **502** may provide various other functions such as integrating the anonymized patient data with existing patient population data in the database **504**.

[0244] The integrated data in database **504** may be accessed by, delivered to, or otherwise utilized by multiple systems and parties. Such systems include for example, commercial systems **104** such as pharmaceutic systems **106***c* and university systems **106***d*. Parties associated with the pharmaceutic systems **106***c* may utilize the patient population data, for example, for statistical analysis and projective capabilities such as determining the efficacy, cost efficiency, profit, etc. of a particular medication and projecting from the determination new product line concepts/therapies, etc. Parties associated with universities may utilize the patient population data to research symptomotology, analyze medication risks, etc.

[0245] In various aspects, the decision support system **204***b*, IEM data system(s), and/or commercial system(s) interoperate, e.g., communicate, therebetween.

[0246] To continue the foregoing illustration, in addition to the provision of decision support data such as patient population data, the decision support system **204***b* communicates patient population data to the feedback loop system **204***a*. The feedback loop system **204***a* communicates the patient population data to mobile telephone **406***a* of patient **506***a*.

[0247] In one scenario, the decision data derived from a patient population such as medication efficacy may be correlated with an individual's medication therapy, and communicated via marketing system specifically targeted for that individual.

[0248] 2.3.3 Auto Refill Systems

[0249] Auto refill systems automatically fill or refill prescriptions. In one example, IEM data identifying an ingested medication are gathered and reconciled with current prescription information to identify depleted prescription supplies. If the supply is depleted, a refill order is automatically triggered to the appropriate pharmacy. The pharmacy automatically refills the order, generates a bill, and charges the appropriate account, e.g., via a real time, online financial transaction.

[0250] FIG. **8** illustrates an exemplary IEM data framework **102** having an auto refill system **204***c*, according to one embodiment. The IEM data framework **102** further includes IEM data **200** and the hub **202**, shown here embodied as the

base station **404**. In various aspects, the auto refill system **204***c* may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

[0251] In one scenario, the patient **506** ingests prescription medication in conjunction with an ingestible device. The ingestible device identifies the medication type and dosage, and transmits the IEM data **200** via, for example, conductive transmission to the patch receiver **400**, which may be removably attached to the patient **506**. The patch receiver **400** transmits the IEM data **200** to base station **404**. The base station **400** forwards the IEM data **200** to the auto refill system **204***c*. The software **502** of the auto refill system **204***c* compares the medication type and dosage of the IEM data **200** against prescription information stored in the database **504**. The prescription information, for example, may include the number of tablets in the prescription at time of fill, the dosage instructions, and a running total of the ingested tablets as per previously received information. If the comparison indicates depletion of the prescription medication, database **504** is checked for the number of remaining refills. If refills are remaining, any sensitive data of the IEM data **200** are cleansed, i.e., removed, and a prescription refill request with pertinent information is compiled and transmitted according to predetermined security protocol and via predetermined channel(s) to a commercial system **106** such as the pharmacy system **106***b*. Upon receipt by the pharmacy system **106***b*, the refill request is parsed and verified, and the prescription is refilled.

[0252] Payment for refill can be effected, for example, via a real-time, online transaction between the pharmacy system **106***b* and an IEM data system **204** and/or commercial system, e.g., financial transaction system **106***e*. The financial transaction system **106***e*, for example, may receive the financial transaction, e.g., prescription refill charge, via a predetermination communication channel. The financial transaction system **106***e* verifies the patient account information and completes the transaction, notifying the pharmacy system **106***b*.

[0253] Notification of status of refill and payment for refill can be provided via predetermined communication channel (s) to the base station **300**, e.g., an email for display on the laptop computer, a text message to the patient's mobile telephone, etc.

[0254] 2.3.4 Patient Tools

[0255] Patient tools include any data, information, software, websites, etc. that provide information or assist a particular patient focus, e.g., tracking tools to assist a patient in cardiac health management, patient personalization of their own data, etc. Various users may be associated with the patient tools. Examples include various users within a patient community, e.g., patients, family caregivers, and professional caregivers such as physicians.

[0256] FIG. **9** illustrates an exemplary IEM data framework **102** having a patient tools **204***d*, according to one embodiment. The IEM data framework **102** further includes IEM data **200***a-c* and the hubs, shown here embodied as the base station **404**, the mobile telephone **406**, and the handheld device **402**. In various aspects, the patient tools **204***d* may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

[0257] In one scenario, multiple parties such as patients **506***a-c* access the patient tools **204***d*, which may be embodied as the server **500** having the software **502** and the database **504** having IEM data **200** in the form of at least patient tools. Patients **506***a-c* may access the patient tools **204***d*, for example, via the base station **404**, the mobile telephone **406**, and the handheld device **402**, respectively.

[0258] Patient **506***b* may search the database **504** for patient tools related to mental illness management. The patient tools, for example, may be provided in the form of downloadable data/applications to assist in tracking, monitoring, diagnosing, and notifying a patient of a relevant health issue, e.g., medication dosage schedule, etc. Patient **506***b* may download the application onto, for example, the mobile telephone **406**. Patient **506***b* may further communicate via, for example, the mobile telephone **406** with at least one commercial system such as the healthcare system **106***a*, which may provide further medical data, instruction, etc., relevant to the patient **506***b*'s mental illness management pursuit.

[0259] In various aspects the patient tools **204***d* may be configured for and utilized by for various parties besides the patient, e.g., a patient community, family caregivers, and professional caregivers.

[0260] 2.3.5 Behavioral Medicine Systems

[0261] Behavioral medicine systems may collect, track, and analyze behavior-related data to identify causal failure points in treatment and to predict corrective action by prescribing specific behavior modifications. In various aspects, the behavioral medicine systems may assist patients via questionnaires and patient profile assessment on symptomatologic or therapeutic subjects, e.g., in various decision processes by display a menu-guided series of questions and receiving answer(s) from the patient.

[0262] FIG. **10** illustrates an exemplary IEM data framework **102** having a behavioral medicine system **204***e*, according to one embodiment. The IEM data framework **102** further includes IEM data **200** and the hub, shown here embodied as the base station **404** and the mobile telephone **406**. In various aspects, the behavioral medicine system **204***e* may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

[0263] In one scenario, the behavioral medicine system **204***e*, e.g., a software agent, may be located in whole or in part on a patient-related device such as the mobile telephone **406**. The software agent may assist the patient in various endeavors, e.g., diet choices, smoking cessation, etc. The assistance may be provided, by example, by generating for display on the mobile telephone **406** question sets related to diet and smoking cessation. The patient may answer the questions, e.g., select from various answer options. Based on the patient's answers to the questions, the software agent may categorize the patient according to predetermined categories. The software agent may provide language and menu choices based on the patient categorization.

[0264] In another scenario, patient behavior is tracked with respect to various IEM data, e.g., patient parameters, sometimes referred to herein as "sentinels for wellness". Examples of sentinels for wellness include medication therapy adherence, weight, blood pressure, etc. The sentinels for wellness may be derived, for example, from various health devices **300***c* such as intelligent scales, cardiac-related devices, etc.

[0265] To illustrate, patient **506** ingests medication according to physician instructions. The IEM data **200** in the

form of ingestion information identifying the ingested medication and the time of ingestion are captured via an ingestion device and communicated to the patient's mobile telephone **406**. Also captured via health device(s) **300***c* at the time of medication ingestion are the patient's blood pressure and weight. The timing of the foregoing data captures may be synchronized via, for example, software utilizing a reminder system to alert the patient to take the medication at a particular time. Upon receiving the ingestion information, e.g., confirmation of ingestion, the software associated with the mobile telephone **406** communicably triggers health device(s) **300***c* to determine blood pressure and weight, and forwards such data to the mobile telephone **406** for aggregation with the IEM data **200** in the form of the ingestion information. The aggregated data may be forwarded to behavioral medicine system **204***e*, which may be configured, for example, as the mobile telephone and software **406**, the server **500** including the software **502** and the database **504**, and/or other configurations. Upon receipt of the aggregated data, various processing may take place.

[0266] One example of processing is analysis of the IEM data **200** to determine degree of patient adherence to medication regimen, i.e., determine if the patient ingested the prescribed medication in the right dosage at the prescribed time interval(s).

[0267] Another example of processing is analysis of the IEM data **200** to determine if the blood pressure measurement is in line with physician expectations. Thus, the notification of patient adherence to the medication regimen and the blood pressure measurement may be communicated to a physician system **106***f* for review by the patient's physician. The physician, in turn, may update the IEM data **200**, e.g., determine an adjustment in the medication regimen is needed and communicate, via the behavioral medicine system, the updated medication regimen to the patient's mobile telephone **406** and to the pharmacy system **106***b* for filling the updated prescription.

[0268] In cases of a nonadherence determination, the physician may alert the patient, via the behavioral medicine system **204***e*, to make an appointment for a physical review. In various aspects, the behavioral medicine system **204***e* may generate and/or forward a reminder to the hub, e.g., mobile telephone **406** of the patient **506**. The reminder, for example, may include the dosing schedule, a reminder for the upcoming dose, instructions to follow in case of a missed dose, etc.

[0269] In cases of underdosage/overdosage, the behavioral medicine system **204***e* may interoperate with an alert system, e.g., the IEM data phone system, infra, and compare current dosage information to predetermined thresholds to determine if a critical status dosing event exists, e.g., the patient is critically underdosed or critically overdosed. If such a determination is made, the appropriate system may generate an alert to appropriate parties, e.g., generate a 911 emergency call for medical assistance, generate an emergency alert to the physician system **106***f*, and generate an alert to a family caregiver system **106***g*, e.g., a family member's mobile telephone.

[0270] In still another scenario, analysis of the patient's communication patterns/habits is performed to determine patient parameters, indicated actions, etc. To illustrate, an application such as software **502** resident on the mobile telephone **406** tracks the patient's phone usage to determine communication patterns. For example, the family caregivers, physician, etc., may selectively configure tracking parameters of the application to determine various patient communication thresholds, patterns, etc. The software monitors communication from/to the selected device, e.g., the patient's mobile telephone **406**. In various aspects, the application mines mobile telephone records of the associated carrier to determine calling and called parties, heavy volume call time, no call times, etc. and builds a profile against the same. The application monitors use of the mobile telephone **406** and identifies significant, e.g., user selected, deviations from the profile. Upon identification of a deviation, the application initiates predetermined actions, e.g., communicates an alert to the physician and/or family caregiver via the healthcare system **106***a*, the physician system **106***f*, and/or the family caregiver system **106***g*.

[0271] Another example of processing is analysis of the IEM data **200** together with data from another source, e.g., aggregated data. The aggregated data may be collected from various sources, aggregated at various and/or multiple points, and/or communicated via various channels to/from various devices.

[0272] To illustrate, cardiac data is derived via electrical tomography, as heretofore discussed. The cardiac data is communicated directly or indirectly, e.g., by the patch receiver **400**, to a software application on the hub, e.g., the mobile telephone **406**. The software application on the mobile telephone **406** aggregates the cardiac data with the IEM data, e.g., pill ingestion-related data, and displays the various data via a graphical user interface (GUI).

[0273] Subsequent to enrollment, the behavioral medicine system ascertains that the patient has neglected to take the medication at the appropriate times. Reminder alerts for upcoming medication dosing time(s) are sent to the patient via the mobile telephone. Upon receiving the alerts, the patient timely ingests the medication, resulting in a change in the sentinels for wellness.

[0274] 2.3.6 Incentive Systems

[0275] Incentive systems provide incentives and rebates through various programs. The incentives and rebates are based on, or otherwise associated with, the IEM data. The IEM data may be analyzed via, for example, an IEM data system **204** to determine if certain criteria/thresholds/goals are evident. Based on the determination, incentives tied to or associated with the criteria/threshold/goals may be generated.

[0276] FIG. **11** illustrates an exemplary IEM data framework **102** having an incentive system **204***f*, according to one embodiment. The IEM data framework **102** further includes IEM data **200** and the hub, shown here embodied as the mobile telephone **406**. In various aspects, the incentive system **204***f* may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

[0277] In one scenario, patient adherence is tracked with respect to various patient parameters, e.g., medication therapy and adherence. Incentives may be awarded accordingly. For example, patient **506** ingests medication according to physician instructions. The IEM data **200** in the form of ingestion information identifying the ingested medication and the time of ingestion are captured via an ingestion device and communicated to the patient's mobile telephone **406**, and to the behavioral medicine system **204***e*. The behavioral medicine system **204***e* verifies patient **506** adherence to the prescribed medication regimen, and sends veri-

fication to the incentive system **204***f*. The incentive system **204***f*, via the software **502** and the database **504**, determines the price paid for the medication, and issues a rebate or credit against the cost. For example, the rebate may be issued and a financial transaction in the amount of the rebate posted to the patient's financial account via the financial transaction system **106***e*.

[0278] In another example, the rebate may be communicated and applied to an account associated with the patient via the pharmacy system **106***b* with, for example, a credit against the next refill for the patient's prescription medication.

[0279] In another example, the patient's blood pressure and weight may be captured via health device(s) **300***c* at time of medication ingestion. The timing of the foregoing data captures may be synchronized via software utilizing a reminder system to alert the patient to take the medication at a particular time. Upon receiving the ingestion information, e.g., confirmation of ingestion, the software associated with the mobile telephone **406** may communicably trigger health device(s) **300***c* to determine blood pressure and weight, and forward such data to the mobile telephone **406** for aggregation with the IEM data **200** in the form of the ingestion information. The aggregated data may be communicated to the incentive system **204***f* where the software **502** and/or database **504** may be utilized to determine if the patient's weight and blood pressure meet acceptable predetermined thresholds. If, for example, the weight exceeds an acceptable threshold, the incentive system **204***f* may generate an incentive in the form of a discount membership offering at a local health club, etc. The offering may be constructed using various data parameters and demographics, e.g., geographical location of the patient, amount of weight to be lost, health assessment scoring based on individualized patient health parameters, lists of participating health clubs, etc.

[0280] The incentive may be communicated to the patient **506** via, for example, the patient's mobile telephone **506**.

[0281] 2.3.7 Personalized Commercial Products/Services

[0282] Personalized commercial products/services provide individualized products and services predicated on or related to IEM data.

[0283] FIG. **12** illustrates an exemplary IEM data framework **102** having a personalized commercial products/services system **204***g*, according to one embodiment. The IEM data framework **102** further includes IEM data **200** and the hub **202**. In various aspects, the commercial products/services system **204***g* may be embodied as, for example, an IEM data device, e.g., a patch receiver. In various aspects, the commercial products/services system **204***g* may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

[0284] In one scenario, commercial products/services system **204***g* include consumer-friendly receivers, such as patch receivers. The receivers comprise various accessories and incorporate various designs. For example, children's patch receivers may comprise cartoon character appliqués. Youths' patch receivers may comprise tattoo-like design aspects. Further examples include IEM data receivers embodied as/integrated into accessories, e.g., earrings, naval rings, and other means of adornment, etc.

[0285] Commercial products/services system **204***g* further comprise branded or "community" associated products and services.

[0286] 2.3.8 Auto Billing Systems

[0287] Auto billing systems receive, process, and/or facilitate payment via a financial account. Auto billing applications associated with the auto billing system and/or with financial institution systems seamlessly interoperate to generate a bill, verify accountholder information, charge an account, etc. Statements are updated to reflect payment information. Similar applications may be applied for prescriptions, consumer products, information provision via personal devices, etc.

[0288] FIG. **13** illustrates an exemplary IEM data framework **102** having an auto billing system **204***h*, according to one embodiment. The IEM data framework **102** further includes IEM data **200** and the hub, shown here embodied as the handheld device **402**. In various aspects, the auto billing system **204***h* may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

[0289] In one scenario, various parties such as patient **506**, physicians, pharmaceutical companies, etc., subscribe to information feeds/patient population data of IEM data **200** to further business goals, manage health care, etc. The parties may receive the information feeds/access population data, etc. via a variety of devices. For example, patient **506** may receive an information feed via hub **202** embodied as the handheld device **402**, which, via a software agent, may generate a financial transaction in the form of an invoice for the information feed displayed for the patient **506**. Payment may be effected via automated methods.

[0290] In a patient selection method, for example, the patient selects various payment options via the software agent resident on the handheld device **402**. A payment transaction is generated and communicated to the financial transaction system **106***e*. The financial transaction system **106***e* automatically charges an account associated with the patient **506**. Confirmation of the payment together with digital, e.g., electronic, copies of the invoice are provided to the software agent resident on the handheld device **402** for the patient **506** to view, etc.

[0291] In an automated method, for example, a bill and/or financial transaction are automatically generated upon predetermined criteria. The predetermined criteria include, for example, delivery of information associated with an information feed or other source, access to a data collection, e.g., patient population data stored in a database, etc. The patient selects various payment options via the software agent resident on the handheld device **402**, and a payment transaction is generated and communicated to the financial transaction system **106***e*. The financial transaction system **106***e* automatically charges an account associated with the patient **506**. Confirmation of the payment together with digital copies of the invoice are provided to the software agent resident on the handheld device **402** for the patient **506** to view, etc. For example, a healthcare provider may access patient population data stored in decision support system **204***b* via the healthcare system **106***a*. Software of the decision support system **204***b* may cooperate with the software **502** and the database **504** of the auto billing system **204***h* to identify the party to be billed for the access. Upon identification, the auto billing system **204***h* may automatically generate a bill and/or financial transaction for the access via one or more of the aforedescribed channels.

[0292] 2.3.9 Tracking Systems

[0293] Tracking systems track and integrate product movement data. In one example, the life cycle of an ingestible device may be tracked from manufacture to shipment, pharmacy inventory, delivery to patient, ingestion and expulsion.

[0294] FIG. **14** illustrates an exemplary IEM data framework **102** having a tracking system **204***i*, according to one embodiment. The IEM data framework **102** further includes the IEM data **200** and the hub, shown here embodied as a scanner **1402**. In various aspects, the tracking system **204***i*, may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

[0295] In one scenario, a pharmaceutical manufacturer produces an ingestible device **302***a* such as a particular medication having an IEM system device therein. The IEM system device contains various IEM data **200** such as medication identification, batch number, lot number, and manufacturer identification. The scanner **1402** may be utilized at various times/locations to scan the ingestible device **302***a* and capture the IEM data **200** associated therewith. The IEM data **200** may then be stored, processed, etc., via, for example, the software **502** and the database **504** of the tracking system **204***i*. For example, the IEM data **200** may be read by the scanner at a shipping point and when received by a pharmacy to ensure inventory control, distribution integrity, and chain of custody for restricted pharmaceuticals, etc.

[0296] The tracking information may be used, for example, by regulatory agencies systems **106***i* to determine regulatory adherence, etc.

[0297] 2.3.10 Interdiction Systems

[0298] Interdiction systems track, reconcile, and support interdiction programs. The interdiction programs include, for example, programs related to drug identification and use detection by sworn personnel, search and seizure activities, etc.

[0299] FIG. **15** illustrates an exemplary IEM data framework **102** having an interdiction system **204***j*, according to one embodiment. The IEM data framework **102** further includes IEM data **200** and hub, shown here embodied as a scanner **1402**. In various aspects, the interdiction system **204***j* may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

[0300] In one scenario, a pharmaceutical manufacturer produces an ingestible device **302***a* such as a particular medication having an IEM system device therein. The IEM system device contains various IEM data **200** such as medication identification, batch number, lot number, and manufacturer identification. The scanner **1402** may be utilized at various times/locations to scan the ingestible device **302***a* and capture the IEM data **200** associated therewith. The IEM data **200** may then be communicated to, for example, the software **502** and the database **504** of the interdiction system **204***j*, where the IEM data **200** may be accessed by and communicated to regulatory agency systems **106***i* to facilitate various regulatory and enforcement functions, to locate missing controlled substances, to intercept contraband, to identify unknown substances, and to otherwise support agency and regulatory activities.

[0301] In various aspects, the IEM data **200** may be communicated to/from, for example the interdiction system **204***j* from/to the tracking system **204***i*, for processing, storage, etc. For example, the IEM data **200** may be read by the scanner at a shipping point and read by a pharmacy to ensure inventory control, distribution integrity, and chain of custody for restricted pharmaceuticals, etc. The scanned (read) IEM data **200** may be reconciled between the interdiction system **204***j* and the tracking system **204***i* to ensure complete shipment, to track shipments through various jurisdictions, etc. In one example, the IEM data **200** such as the identifier data, shipment data, patient information, recipient information, and commercial activities are tracked and reconciled to intercept contraband and otherwise support agency and regulatory activities.

[0302] 2.3.11 Subscription Systems

[0303] Subscription systems enable subscription to various IR information feeds and data/knowledge collections, e.g., IEM data collection system. For example, patients subscribe to IEM data information feeds and/or IEM data collections, which aggregate various sources of data and fuse the data into integrated, individualized information based on the subscriber's requirements. The information fusion may include, for example, personalized medication regimens and alert applications, individual social community information, music, etc. The information may be automatically billed, for example, under a single point of charge model on a recurring basis. The agent may be provided as part of an embedded device, e.g., standard application on a mobile telephone, etc.

[0304] FIG. **16** illustrates an exemplary IEM data framework **102** having a subscription system **204***k*, according to one embodiment. The IEM data framework **102** further includes IEM data **200** and the hub, shown here embodied as a mobile telephone **406**. In various aspects, the subscription system **204***k* may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

[0305] In one scenario, the patient **506** subscribes to various information feed(s) and/or IEM data collections, discussed hereinafter in detail. The information feed(s) include, for example, structured and non-structured information on a variety of topics generated or delivered from various sources, e.g., websites, blogs, etc. The IEM data collections include storage repositories having IEM data. The storage repositories may be associated, e.g., integral to or remote from, the subscription system **204***k*. For example, an IEM data collection may be resident in part or wholly in database **504** of the subscription system **204***k*.

[0306] In one scenario, IEM data **200** are communicated from a subscription source to a subscriber, e.g., a subscriber's device. The subscription source includes, for example, IEM data systems **204**, e.g., the database **504** of the subscription system **204***k*, feedback loop system **204***a*, patient tools **204***d*, and decision support system **204***b*; commercial systems **106***b*, e.g., online medical and business information/newsfeed sources, healthcare system **106***a*; and other sources, e.g., devices associated with the patient **506**, the hub, etc. The subscriber includes, for example, a person, group, or resource, e.g., a database, a computer system, server, network, etc.

[0307] In various aspects, subscription services may be initiated via, for example, a software agent resident on the hub or communication with a local or remote system such as the healthcare system **106***a*.

[0308] In various aspects, the subscriptions services may be billed and paid via, for example, the subscription system **204***k* and the financial transaction system **106***e*.

[0309] In various aspects, the subscription newsfeeds/data may be combined or integrated into a single or multiple newsfeeds, e.g., the software **502** and/or the database **504** of the subscription system **204***k* may enable data aggregation, etc.

[0310] To illustrate, the patient **506** subscribes to a healthcare newsfeed and a pharmacy newsfeed, one or more having IEM data **200**, via the subscription system **204***k*. The patient subscribes by selecting an application, e.g., software agent resident on the hub, illustratively embodied here as the mobile telephone **406**. Once the patient has selected the subscription options, the order is communicated to the subscription system **204***k*, which, via the software **502** and the database **504**, confirms, processes, stores, and bills the order. The subscriber's financial account may be automatically charged, for example, by communicating invoice information to a financial transaction system **106***e* associated with the subscriber's account. Confirmation of the charge may be communicated from the financial transaction system **106***e* to the subscriber via the subscription system **204***k* and/or the mobile telephone **406**.

[0311] Based on the subscription parameters, the subscription system **204***k* receives the healthcare newsfeed information and the pharmacy newsfeed information. The software **502** of the subscription system compares subscriber data of the patient **506** in the database **504** against subscriber data found in the pharmacy newsfeed, e.g., patients who are prescribed medications for cardiac therapy. Based on the comparison, software **502** separates the data of the pharmacy newsfeeds relevant to the subscriber, combines the relevant data with the healthcare newsfeed information and communicates the combined newsfeed information to the mobile telephone **406** for access and display.

[0312] 2.3.12 IEM Data Collection System

[0313] The IEM data collection system provides/facilitates access to/storage of the IEM data. Examples of the IEM data include patient population data and electronic medical records. In various aspects, IEM data collections may include functionality related to the collection, management, manipulation, storage, dissemination, and billing of IEM data.

[0314] FIG. **17** illustrates an exemplary IEM data framework **102** having an IEM data collection system **204***l*, according to one embodiment. The IEM data framework **102** further includes IEM data **200** and the hub, shown here embodied as a handheld device **402**. In various aspects, the IEM data collection system **204***l*, may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

[0315] In one scenario, patient population data, e.g., anonymized, empirical patient data, is stored in one or more repositories, e.g., the database **504** of the IEM data collection system **204***l*. The patient population data may be received from various sources, e.g., the IEM data **200** associated with one or more patient **506**, IEM data systems **204** such as behavioral medicine systems **204***e*, subscription systems **204***k*, patient tools **204***d*, etc., and commercial systems such as healthcare systems **106***a*, pharmaceutic systems **106***c*, university systems **106***d*, etc.

[0316] In various aspects, the IEM data collection system **204***l* may be consolidated in a single physical and/or logical location, e.g., the database **504** of the server **500** of the IEM data collection system **204***l*, or distributed across two or more systems or locations, e.g., remotely distributed on multiple IEM data systems **204**, associated with commercial systems **106**, and/or distributed between the IEM data collection system **204***l* and other systems/locations.

[0317] Multiprofile users may access, utilize, and/or contribute to the IEM data collection system **204***l*. Multiprofile users include, for example, individuals or groups using various methods/devices for access, utilization, and/or contribution. Examples of multiprofile users include patient **506**, family members and family caregivers, professionals, academics, corporates, etc. The methods/devices include the hub devices such as a mobile telephone, base station, handheld device, etc., as well as system components associated with IEM data systems and commercial systems, e.g., laptop computer associated with a university network, a desktop computer associated with the family caregiver system **106***g*, etc.

[0318] To continue the foregoing illustration, a researcher, using the university system **106***d*, accesses the IEM data collection system **204***l* via the Internet, etc. and submits queries against the patient population data, extracts various data, etc.

[0319] In various aspects, the IEM data collection system **204***l* includes privacy assurance, authentication, and validation mechanisms with respect to financial, medical, and other privacy information. For example, the software **502** may authenticate users. The software **502** may cleanse/verify data to ensure predetermined privacy thresholds are met.

[0320] 2.3.13 Approval Systems

[0321] Approval systems aggregate and/or analyze various data to enable an informed approval decision.

[0322] FIG. **18** illustrates an exemplary IEM data framework **102** having an approval system **204***m*, according to one embodiment. The IEM data framework **102** further includes IEM data **200**, the hub, shown here embodied as a handheld device **402**, and an associated intelligent pill dispenser **1802**. In various aspects, the approval system **204***m*, may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

[0323] In one scenario, the patient **506** opens an intelligent pill dispenser **1802**, e.g., a pill dispenser having a microchip and communication abilities. The patient **506** removes a pill having an IEM system from the intelligent pill dispenser **1802**. The intelligent pill dispenser **1802**, via its microchip, senses the removal of the pill, receives a signal from an IEM system that the patient **506** has ingested the pill, and determines the remaining quantity. If the remaining quantity is fewer than a predetermined threshold quantity, the intelligent pill dispenser **1802** communicates a refill request to the approval system **204***m*. The approval system **204***m* via, for example, the software **502** and the database **504**, verify information associated with the patient **506**, e.g., patient name, prescription identification, medication ingestion verification, refill timing, etc. The approval system **204***m* may interoperate with, e.g., communicate with, various IEM data systems **204** and/or commercial systems **106** to obtain/validate information. For example, data provided to/resident in the approval system **204***m* may be reconciled with medical records of healthcare system **106**, the refill request approved by approval system **204***m*, and a refill communicated to the pharmacy system **106***b*.

[0324] 2.3.14 Forecasting Systems

[0325] Forecasting systems aggregate data and/or facilitate analysis of the aggregated data/data collections to derive/generate predictive information.

[0326] FIG. **19** illustrates an exemplary IEM data framework **102** having a forecasting system **204***n*, according to one embodiment. The IEM data framework **102** further includes IEM data **200** and the hub, shown here embodied as a base station **404**. In various aspects, the forecasting system **204***n*, may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

[0327] In one scenario, for example, IEM data **200** are received by the base station **404** from ingestible devices associated with patients **506***a-c*. The base station **404** communicates the IEM data **200** to the IEM data collection system **204***l*, which anonymizes the IEM data **200** and aggregates the anonymized IEM data **200** with patient population data.

[0328] The IEM data collection system **204***l* communicates all or a portion of the patient population data to the forecasting system **204***n*, where the software **502**, e.g., one or more applications, processes the patient population data to derive various statistics, conclusions, forecasts, etc., according to predetermined requirements, objectives, etc. For example, the software **502** processes the patient population data and correlates various data such as blood pressure readings over a predetermined period of time versus medication taken versus adherence to medication regimen to determine overall efficacy of medication regimen and to forecast titrated patient dosing based on the overall efficacy findings.

[0329] Multiple profile parties, e.g., analysts using the pharamceutic systems **106***e*, agents using the regulatory agency systems **106***i*, and researchers using the university systems **106***d*, access the forecasting system **204***n*. The multiple profile parties utilize various tools, e.g., the software **502**, to run analytical and forecasting applications again the patient population data and to access various forecasting data available in connection with the forecasting system **204***n*.

[0330] 2.3.15 Financial Systems

[0331] Financial systems support and enable financial transactions associated with IEM data. In various aspects, the financial systems are communicably interoperable with existing automated banking systems and networks, etc.

[0332] FIG. **20** illustrates an exemplary IEM data framework **102** having a financial system **204***o*, according to one embodiment. The IEM data framework **102** further includes IEM data **200** and the hub, shown here embodied as a mobile telephone **406**. In various aspects, the financial system **204***o*, may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

[0333] In one scenario, the patient **506**, via the mobile telephone **406**, places an order for a product/service, e.g., a newsfeed service from the subscription system **204***k*. The subscription system **204***k*, via its software, interoperates with the financial system **204***o*. The subscription system **204***k*, for example, securely communicates encrypted patient financial information such as account number and subscription information. The financial system **204***o* authenticates the patient information and securely interoperates with the patient's financial institution, e.g., via a commercial system **106** such as the financial transaction system **106***e* to charge the patient's account and provide charge information/confirmation to the patient **506** via, for example, the mobile telephone **406**.

[0334] 2.3.16 IEM Data Phone

[0335] The IEM data phone enables IEM data—related applications. For example, application(s) include pill regimen scheduling applications, alert reminder applications, auto refill for medication applications, patient tool applications, social networking applications, incentive tracker applications, auto billing applications, subscription applications, approval applications, and financial transaction applications. The applications may be integrated with, associated with, or independent of one another. The applications may further be manufacturer-installable on the IEM data phone, downloadable or otherwise installable by a wholesaler, retailer, user, etc. Installation may be independent or bundled with other software, products, etc. In various aspects, the applications are user-configurable, downloadable, upgradeable, etc.

[0336] In various aspects, the IEM data phone and/or its applications may share common features, e.g., a common graphical user interface (GUI); branding, i.e., a collection of images and ideas representing an economic producer such as concrete symbols embodied as a name, logo, slogan, design scheme, etc. The IEM data phone may also include various connectivity schemes, e.g., Internet and cellular; may provide multimedia capabilities; and may embody various hardware and software configurations. The IEM data phone may be embodied in a variety of devices, e.g., the mobile telephone **406**, the handheld device **402**, etc.

[0337] FIG. **21** illustrates an exemplary IEM data framework **102** having an IEM data phone **204***p*, according to one embodiment. The IEM data phone **204***p* may serve as the hub, for example. IEM data framework **102** further includes IEM data **200**. In various aspects, the IEM data phone **204***p*, may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

[0338] In one scenario, the IEM data phone **204***p* includes the software **502**, e.g., a portfolio of branded applications such as pill regimen scheduling, alert reminders, auto refills, patient tools, social networking, incentive trackers, auto billing, subscriptions, approvals, and financial applications.

[0339] The pill regimen scheduling application may accept, reconcile, calendar, and manage contraindications and interactions of medication regimen(s). For example, the patient **506** may input information related to one or more prescriptions, including the pharmaceutical name and dosage. The pill regimen scheduling application may check the input information against existing information stored on the IEM data phone **204***p*, e.g., in the database **504**, or elsewhere, e.g., the pharmacy **106***b*. The pill regimen scheduling application may provide information regarding contraindicated medications, side effects, precautionary instructions. The pill regimen scheduling application may calendar the dosing information and generate alerts, e.g., reminders generated at appropriate times alerting the patient to ingest the medication. The alerts may be audible, visual, email, text message, etc. and may be integrated with, or independent of, alert reminder application(s).

[0340] The alert reminder application may accept or access various data associated with scheduling, including IEM data **200**, and generate alerts at appropriate times. The

alerts may be audible, visual, email, text message, etc. and may be integrated with or independent of alert reminder application(s). The alert application may be user-configurable, e.g., type of alert, repetition of alert, interval of repetition, receivers of alert. The alerts may be associated with various devices of the patient, family caregivers, friends, etc. In one example, the patient **506** may schedule reminders to be sent to the user's device, e.g., the IEM data phone **204***p*, the handheld device **402**, the base station **404**, the mobile telephone **406**, etc.

[0341] The alert reminder application may be integrated with other applications/systems. To illustrate an IEM system associated with the patient **506** that may, for example, detect medication ingestion event(s) and communicate the IEM data **200** associated with the medication ingestion event(s) to the alert reminder application via the IEM data phone **204***p*. The alert reminder application may interoperate with the pill regimen scheduling application and perform various checks, e.g., the ingested medication was actually prescribed for the person that ingested it; the ingested medication was ingested in the correct dosage; the ingested medication was ingested at the prescribed time interval; etc.

[0342] Predetermined criteria may be used to determine if/when the alert reminders application generates an alert, reminder, etc. To continue with the foregoing illustration, upon a determination that the ingested medication was not prescribed for the person ingesting it or the wrong dosage was ingested, the alert reminder system generates alert(s) to a predetermined destination, e.g., alerts in the form of text messages to mobile telephones associated with the family caregiver system **106***g*, alerts in the form of email/text messages to the healthcare system **106***a* and the physician system **106***f*. If the event is deemed critical, e.g., ingestion of non-prescribed medication, overdosage, etc., the alert reminder application may generate a call from the IEM data phone **204***p* to the emergency assistance system, e.g., place a 911 call. The call (prerecorded audio, text message, etc.) may contain information such as the patient's name, the nature of the emergency, the ingestion details, physician and family caregiver information, and the physical location of the person ingesting the medication.

[0343] The auto refill application may facilitate automatic refill of a prescription medication via interoperation with, for example, the pharmacy system **106***b*, etc.

[0344] The patient tool application may be provided on or accessible from the IEM data phone **204***p*. For example, software tools for tracking dietary and physiologic symptoms may facilitate user entry of dietary intake and symptoms, collection of device-associated physiologic parameters such as blood pressure, heart rate, etc., correlation/analysis of the data, and feedback based on the correlation/analysis. The patient tool application may provide data, e.g., the feedback, for display on the IEM data phone **204***p*, the IEM data system(s) **204**, and/or the commercial system(s) **106**.

[0345] The social networking application may facilitate social networking functionality. For example, the social networking application may retain various links to selected profiles of various social networks, receive data related to the selected profiles, e.g., updates to the profiles, facilitate messaging and other communication, update the user's profile, etc., communicate with the IEM data systems(s) **204**, and/or the commercial system(s) **106**, such as the patient tools/social network **204***d* and the web communities **106***h*.

[0346] The incentive tracker application may collect, manage, track, update, etc. incentive information. For example, the incentive tracker application may reconcile data associated with IEM data collection systems **204***l* and wholesaler/retailer systems **106***j* to determine incentive eligibility, e.g., a patient rebate. The incentive tracker application may further tally points under various reward systems, notify the patient **506** of milestones, goals, award of incentive, etc.

[0347] The auto billing application may facilitate billing for various transactions. The auto billing application may interoperate with various applications/systems, including the IEM data system(s) **204** and/or the commercial system(s) **106**, such as the billing for an auto refill via the pharmacy system, etc.

[0348] The subscription application facilitates ordering, receipt, management, etc. of various subscriptions, e.g., newsfeeds, access to various data collections on a subscription basis, etc. The subscriptions application may interoperate with various applications/systems, including the IEM data system(s) **204** and/or the commercial system(s) **106**, such as the subscription system **204***k*, the IEM data collection system **204***l*, etc.

[0349] The approval application aggregates and/or analyzes various sources of data to enable an informed approval decision. The approvals application may interoperate with various applications/systems, including the IEM data system (s) **204** and/or the commercial system(s) **106**, such as the auto refill system **204***c*, the subscription system **204***f*, the financial systems **204***o*, the pharmacy systems **106***b*, the wholesaler/retailer systems **106***j*, etc.

[0350] The financial application supports and enables financial transactions associated with IEM data **200**. The financial application may interoperate with various applications/systems, including the IEM data system(s) **204** and/or the commercial system(s) **106**, such as the auto refill system **204***c*, the incentive system **204***f*, the subscription system **204***k*, the approval system **204***m*, the financial systems **204***o*, the pharmacy system **106***b*, the wholesaler/retailer systems **106***j*.

[0351] 2.3.17 Social Network System

[0352] Social networks are a social structure made of one or more nodes, e.g., components such as websites, accessed by individuals or organizations. The social network is typically tied by one or more specific types of interdependency, such as epidemiology, therapeutic regimen, healthcare management, etc., and thus may attract the interest of otherwise unrelated individuals and groups having in common an interest in the interdependencies. Social networks may be built around various communities, e.g., family caregivers, patients, medical conditions, etc.

[0353] One example of a social network is a patient information community that provides information related to a particular medical condition, treatments, medications, regimens, and side effects based on both provider and anecdotal data. The availability of such data may provide benchmark-type services, e.g., facilitate self-assessment of personal progress and adjustment in therapies and behaviors by comparing and contrasting an individual's progress with the particulars of others having the same condition, similar therapies, etc.

[0354] FIG. **22** illustrates an exemplary IEM data framework **102** having a social network system **204***q*, according to one embodiment. The IEM data framework **102** further includes IEM data **200**, and the hub, shown here embodied

as the base station **404**. In various aspects, the social network system **204***q* may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

[0355] In one scenario, patient **506** suffers from a cardiac condition. The patient **506** accesses the social network system **204***q*, which may be embodied as the server **500** having the software **502** and the database **504** having IEM data **200**. Patient **506** may access the social network system **204***q*, for example, via the base station **404**. The patient **506***a* searches the database **504** for patient profiles also having cardiac conditions similar to that of patient **506**. The social network system **204***q* provides multiple profiles of patients having similar conditions. The profiles include various data pertinent to each patient such as medication therapies, personal behavior histories, etc. The patient **506** requests a comparison of his medication therapy, medication therapy adherence, and behavior to that listed in the profiled. The social network system **204***q* provides the requested comparative data in the form of a graphical display. From the display, the patient **506** is able to determine the profiles having the most favorable treatment outcomes. From such profiles, the patient **506** and/or social network system **204***q* analyze the differences between his medication, medication therapy adherence, behavior, etc. and the corresponding interdependencies of the profiles having the most favorable treatment outcomes. The analysis may contrast the differences found in various areas, as well as generate prescriptive advice, e.g., in which areas the patient **506** may want to adjust and specific adjustments based on the analysis. The patient **506** may adopt the prescriptive advice, i.e., adjust accordingly, to improve his own personal outcome. Further, the patient **506** may update the social network system **204***q* with the adjustment data, which may be used in the future for tracking personal improvement as well as benchmarking purposes by other individuals. In various aspects, the social network system **204***q* may be communicably associated with other web communities **106***h*, e.g., youth communities, business communities, etc.

3.0 IEM Data Framework Method

[0356] One aspect comprises, for example, receiving, via a hub, ingestible event data that originates from multiple ingested event markers; and communicating, via the hub, at least a portion of the ingestible event marker data to at least one ingestible event marker data system.

4.0 IEM Data Framework Article

[0357] One aspect comprises, for example, a storage medium having instructions, that when executed by a computing platform, result in execution of a method of utilizing ingestible event marker data, comprising: receiving, via a hub, the ingestible event data that originates from multiple ingested event markers; and communicating, via the hub, at least a portion of the ingestible event marker data to at least one ingestible event marker data system.

5.0 IEM Data Framework System

[0358] One aspect comprises, for example, a receive module to receive, via a hub, ingestible event data that originates from multiple ingested event markers; and a communicate module to communicate, via the hub, at least a portion of the ingestible event marker data to at least one ingestible event marker data system.

[0359] Further, any of the embodiments disclosed herein may be performed in a data processing system. To illustrate, a diagrammatic system comprises, for example, a processor, a main memory, a static memory, a bus, a video display, an alpha-numeric input device, a cursor control device, a drive unit, a signal generation device, a network interface device, a machine readable medium, instructions and a network, according to one embodiment.

[0360] The diagrammatic system may indicate a personal computer and/or a data processing system in which one or more operations disclosed herein may be performed. The processor may be a microprocessor, a state machine, an application-specific integrated circuit, a field programmable gate array, etc. The main memory may be a dynamic random access memory and/or a primary memory of a computer system. The static memory may be a hard drive, a flash drive, and/or other memory information associated with the data processing system.

[0361] The bus may be an interconnection between various circuits and/or structures of the data processing system. The video display may provide graphical representation of information on the data processing system. The alpha-numeric input device may be a keypad, a keyboard and/or any other input device of text, e.g., a special device to aid the physically challenged. The cursor control device may be a pointing device such as a mouse. The drive unit may be a hard drive, a storage system, and/or other longer term storage subsystem. The signal generation device may be a bios and/or a functional operating system of the data processing system. The network interface device may be a device that may perform interface functions such as code conversion, protocol conversion and/or buffering required for communication to and from the network. The machine readable medium may provide instructions on which any of the methods disclosed herein may be performed. The instructions may provide source code and/or data code to the processor to enable any one/or more operations disclosed herein.

[0362] Although the present embodiments have been described with reference to specific example embodiments, it will be evident that various modifications and changes may be made to these embodiments without departing from the broader spirit and scope of the various embodiments. For example, the various devices, modules, etc. described herein may be enabled and operated using hardware circuitry, e.g., CMOS based logic circuitry, firmware, software and/or any combination of hardware, firmware, and/or software, e.g., embodied in a machine readable medium.

[0363] For example, the various electrical structure and methods may be embodied using transistors, logic gates, and electrical circuits, e.g., Application Specific Integrated circuitry (ASIC) and/or in Digital Signal Processor (DSP) circuitry. For example, the receive module and the communicate module and other modules may be enabled using one or more of the technologies described herein.

[0364] In addition, it will be appreciated that the various operations, processes, and methods disclosed herein may be embodied in a machine-readable medium and/or a machine accessible medium compatible with a data processing system, e.g., a computer system, and may be performed in any

order. Accordingly, the specification and drawings are to be regarded in an illustrative rather than a restrictive sense.

[0365] Any or all data associated with the aforementioned devices and methods, for example, may be used alone or in combination with other data to constitute IEM data, i.e., data having an IEM data aspect.

[0366] In certain embodiments, the system and/or method steps further includes/utilizes an element for storing data, i.e., a data storage element, where this element is present on an external device, such as a bedside monitor, PDA, smart phone, computer server, etc. Typically, the data storage element is a computer readable medium. The term "computer readable medium" as used herein refers to any storage or transmission medium that participates in providing instructions and/or data to a computer for execution and/or processing. Examples of storage media include floppy disks, magnetic tape, CD-ROM, a hard disk drive, a ROM or integrated circuit, a magneto-optical disk, or a computer readable card such as a PCMCIA card and the like, whether or not such devices are internal or external to the computer. A file containing information may be "stored" on a computer readable medium, where "storing" means recording information such that it is accessible and retrievable at a later data by a computer and/or computer-related component. With respect to computer readable media, "permanent memory" refers to memory that is permanent. Permanent memory is not erased by termination of the electrical supply to a computer of processor. Computer hard-drive ROM, i.e., not used as virtual memory, CD-ROM, floppy disk and DVD are all examples of permanent memory. Random Access Memory (RAM) is an example of non-permanent memory. A file in permanent memory may be editable and re-writable.

[0367] Also provided are computer executable instructions, i.e., programming, for performing the above methods, e.g., for programming the IEM, receiver, and other components of the system. The computer executable instructions are present on a computer readable medium. Accordingly, various aspects provide a computer readable medium containing programming for use in providing ingestible event marker data.

[0368] As such, in certain embodiments the systems include one or more of: a data storage element, a data processing element, a data display element, a data transmission element, a notification mechanism, and a user interface. These elements may be present or otherwise associated with at least one of the ingestible event marker data, the hub, and the IEM data systems.

[0369] One of the above-described systems is reviewed in terms of a receive module and a communicate module. The aspects, however, are not so limited. In a broader sense, the systems are composed of two or more different modules that communicate with each other, e.g., using the hub functionalities as reviewed above, e.g., using the IEM data in the communication, e.g., using the IEM data systems' functionalities.

[0370] It is to be understood that this invention is not limited to particular embodiments described, and as such may vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present invention will be limited only by the appended claims.

[0371] Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range, is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges and are also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the invention.

[0372] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present invention, representative illustrative methods and materials are now described.

[0373] All publications and patents cited in this specification are herein incorporated by reference as if each individual publication or patent were specifically and individually indicated to be incorporated by reference and are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited. The citation of any publication is for its disclosure prior to the filing date and should not be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

[0374] It is noted that, as used herein and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise. It is further noted that the claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as "solely," "only" and the like in connection with the recitation of claim elements, or use of a "negative" limitation.

[0375] As will be apparent to those of skill in the art upon reading this disclosure, each of the individual embodiments described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other several embodiments without departing from the scope or spirit of the present invention. Any recited method can be carried out in the order of events recited or in any other order which is logically possible.

[0376] Although the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it is readily apparent to those of ordinary skill in the art in light of the teachings of this invention that certain changes and modifications may be made thereto without departing from the spirit or scope of the appended claims.

[0377] Accordingly, the preceding merely illustrates the principles of the invention. It will be appreciated that those skilled in the art will be able to devise various arrangements which, although not explicitly described or shown herein, embody the principles of the invention and are included within its spirit and scope. Furthermore, all examples and conditional language recited herein are principally intended to aid the reader in understanding the principles of the invention and the concepts contributed by the inventors to

furthering the art, and are to be construed as being without limitation to such specifically recited examples and conditions. Moreover, all statements herein reciting principles, aspects, and embodiments of the invention as well as specific examples thereof, are intended to encompass both structural and functional equivalents thereof. Additionally, it is intended that such equivalents include both currently known equivalents and equivalents developed in the future, i.e., any elements developed that perform the same function, regardless of structure. The scope of the present invention, therefore, is not intended to be limited to the exemplary embodiments shown and described herein. Rather, the scope and spirit of present invention is embodied by the appended claims.

1-26. (canceled)

27. A compliance system, comprising:

an ingestible event marker (IEM) device configured to:

generate IEM data after ingestion by an individual, wherein the IEM data comprises first physiologic data associated with the individual; and

transmit a signal comprising the IEM data through the body of the individual; and

a receiver associated with the individual, wherein the receiver is configured to:

receive the signal comprising the IEM data from the IEM device;

measure second physiologic data associated with the individual, wherein at least a portion of the first physiologic data is comparable to at least a portion of the second physiologic data to verify that the individual has ingested the IEM device.

28. The compliance system of claim **27**, wherein the first physiologic data and the second physiologic data are associated with a same physiologic parameter.

29. The compliance system of claim **28**, wherein the physiologic parameter comprises at least one of a heart rate variability, a breathing rate, or a heart rate pattern associated with the individual.

30. The compliance system of claim **29**, wherein the heart rate pattern comprises an ECG pattern.

31. The compliance system of claim **27**, wherein the IEM device comprises an IEM integrated with a medication, and wherein the at least a portion of the first physiologic data is comparable to the at least a portion of the second physiologic data to verify that the individual has ingested the medication.

32. The compliance system of claim **27**, wherein the first physiologic data is measured by the IEM device in temporal proximity to a time of ingestion of the IEM device.

33. The compliance system of claim **27**, wherein the IEM device is configured to wirelessly transmit the signal to the receiver.

34. The compliance system of claim **27**, wherein the IEM device comprises an IEM storing a unique identifier, wherein the unique identifier comprises a data sample reflecting a physiologic pattern associated with the individual, and wherein the IEM data transmitted to the receiver comprises the unique identifier.

35. The compliance system of claim **34**, wherein the data sample comprises at least one of a data sample reflecting a heart rate variability of the individual, a data sample reflecting a breathing rate of the individual, or a data sample reflecting a heart rate pattern of the individual.

36. The compliance system of claim **35**, wherein the data sample reflecting the heart rate pattern of the individual comprises an ECG pattern.

37. The compliance system of claim **34**, wherein the receiver is further configured to:

generate a physiologic identifier for the individual based on the second physiologic data; and

compare the unique identifier received from the IEM device to the generated physiologic identifier to verify that the individual associated with the physiologic pattern has ingested the IEM device.

38. The compliance system of claim **37**, wherein the IEM device comprises an IEM integrated with a medication, and wherein the receiver is configured to compare the unique identifier to the physiologic identifier to verify to verify that the individual has ingested the medication.

39. The compliance system of claim **34**, further comprising:

a data source device associated with the body of the individual, wherein the data source device is configured to generate at least one actual data sample of a physiologic pattern from the individual, and wherein the receiver is further configured to receive the at least one actual data sample from the data source device; and

an IEM system in communication with the receiver, wherein the IEM system is configured to:

receive the at least one actual data sample and the unique identifier from the receiver; and

compare the at least one actual data sample to the unique identifier to verify that the IEM device was actually ingested by the individual.

40. The compliance system of claim **27**, wherein the receiver comprises a personal signal receiver external to the body of the individual.

41. A compliance system, comprising:

an ingestible event marker (IEM) device configured to:

generate IEM data after ingestion by an individual, wherein the IEM data comprises first physiologic data associated with the individual; and

transmit a first signal comprising the IEM data through the body of the individual;

a data source device associated with the body of the individual, wherein the data source device is configured to:

generate second physiologic data associated with the individual; and

transmit a second signal comprising the second physiologic data; and

a receiver associated with the individual, wherein the receiver is configured to receive the first signal from the IEM device and the second signal from the data source device.

42. The compliance system of claim **41**, wherein the first physiologic data and the second physiologic data are associated with a same physiologic parameter.

43. The compliance system of claim **42**, wherein the physiologic parameter comprises at least one of a heart rate variability, a breathing rate, or an ECG pattern associated with the individual.

44. A method of monitoring compliance, comprising:

transmitting a first signal from an ingestible event marker (IEM) device through the body of an individual, wherein the first signal comprises IEM data generated by the IEM device after ingestion by the individual, and

wherein the IEM data comprises first physiologic data associated with the individual;

transmitting a second signal from a data source device associated with the body of the individual, wherein the second signal comprises second physiologic data associated with the individual; and

receiving the first signal and the second signal by a receiver associated with the individual.

45. The method of claim **44**, wherein the first physiologic data and the second physiologic data are associated with the same physiological parameter, wherein the physiologic parameter comprises at least one of a heart rate variability, a breathing rate, or an ECG pattern associated with the individual.

46. The method of claim **44**, further comprising:

comparing at least a portion of the data from the first signal to at least a portion of the data from the second signal to verify that the individual has ingested the IEM device.

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